February 15, 2024

Alkermes Q4 2023 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, 2023. With me today are Richard Pops, our CEO, Todd Nichols, our Chief Commercial Officer and Blair Jackson, our Chief Operating Officer, who will be reviewing our financial results and expectations while our Chief Financial Officer Iain Brown is on medical leave.

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 Richard for some opening remarks.

Richard Pops:

2023 was an eventful and productive year at Alkermes in which we repositioned the company and established a strong foundation for growth. We had an ambitious agenda last year, and we successfully achieved the major goals we set for ourselves.

- We entered 2023 in arbitration with JNJ and prevailed in that matter decisively, which reinstated significant cash flows due to us, strengthened our balance sheet and enabled us to raise our financial expectations.
- We had another pending matter relating to VIVITROL's patent protection, which we also resolved on favorable terms.
- We entered the year with the goal of generating critical decision-making data for our orexin 2 receptor agonist, ALKS 2680, in a multifaceted phase 1 program. We were successful in doing that, generating narcolepsy type 1 data that support advancing into phase 2 in NT1 this year.
- We completed the separation of our oncology business, a major milestone for the company, freeing resources and focusing our R&D efforts in neuroscience.
- We delivered on a significant element of our multi-year initiative to drive operational efficiency by announcing the sale of our Athlone, Ireland GMP manufacturing facility, and that transaction is expected to close mid-year.

- And we also met our goal of continuing to drive our top line revenue from proprietary products, including the continued strong launch of LYBALVI.

Through these accomplishments, we emerged as a pure-play neuroscience company. Today, Alkermes can be characterized by three distinctive attributes.

- First, a commerical business with revenues over $1 billion driven by four core products, all developed by Alkermes;
- Second, proven development capabilities with an advancing neuroscience pipeline;
- And third, an efficient operating structure that positions the business for sustained profitability and significant cash generation.

Todd Nichols:

I am pleased to share that we achieved strong year-over-year growth of 18% across our proprietary commercial portfolio in 2023, as we executed our commercial strategy for each of our three proprietary products and continued to demonstrate the operating leverage we are able to capture with our commercial infrastructure.

Starting with LYBALVI. LYBALVI was the fastest growing oral atypical antipsychotic in the fourth quarter and for the full year. We launched LYBALVI two years ago with a broad, differentiated label that includes both schizophrenia and bipolar I disorder. In its second full year of launch, LYBALVI generated net sales of $191.9 million. For the fourth quarter, net sales

increased 11% sequentially to $56.2 million driven primarily by demand. Prescriptions grew to approximately 46,700 TRxs for the fourth quarter, reflecting 11% sequential growth.

During the quarter, inventory in the channel increased slightly, reflecting a normalization from lower levels at the end of Q3 and typical seasonal purchasing patterns. Gross-to-net adjustments widened to approximately 29% due to higher Medicaid utilization and certain one-time adjustments related to prior periods.

In disease areas as complex and competitive as schizophrenia and bipolar I disorder, new medicines need to establish their place in the treatment paradigm through health care provider experience. We recently shared data from a long-term, phase 3 open-label extension study in which patients with schizophrenia or bipolar I disorder treated with LYBALVI for up to four years demonstrated stability in their symptoms, and minimal changes in their body weight, lipid and glycemic parameters, and a safety profile that was consistent with what we had seen in previous studies. The data highlight the potential utility of LYBALVI as a foundational maintenance treatment option for people living with schizophrenia or bipolar I disorder and we look forward to sharing more data from the study at upcoming medical meetings.

Looking ahead, in 2024 we expect LYBALVI net sales in the range of $275 to $295 million. For the first quarter of 2024, we expect net sales growth to be fairly flat compared to Q4 due to typical seasonal patterns, with more robust growth resuming in Q2.

Turning to the ARISTADA product family. In 2023, ARISTADA net sales grew 8% year-over-year to $327.7 million. ARISTADA net sales in the fourth quarter grew 5% year-over-year to $83.4 million, driven primarily by demand growth of approximately 5% on a months-of-therapy basis.

For 2024, we expect ARISTADA net sales in the range of $340 to $360 million as we continue to emphasize ARISTADA's differentiated value proposition, including its once every two-month dosing option and the ARISTADA INITIO initiation regimen, both of which are supported by clinical data from our ALPINE study.

Moving to VIVITROL. In 2023, VIVITROL net sales grew 6% year-over-year to $400.4 million, driven primarily by unit growth. VIVITROL net sales in the fourth quarter were flat year-over-year at $102.4 million. During the year, VIVITROL growth was driven primarily by the alcohol dependence indication which accounts for approximately 75% of the volume. Growth in the alcohol dependence indication was partially offset by erosion in the opioid dependence indication. As we look ahead, we expect these market dynamics to persist and expect VIVITROL net sales in the range of $410 to $430 million for 2024. Alcohol dependence is an important growth opportunity and our team remains energized about driving awareness and uptake in that under-served disease area.

In 2024, we expect to achieve an important milestone for the company by generating more than $1 billion in proprietary net sales. Each of our proprietary products provides important

contributions to the growth of the company. We are focused on executing across the portfolio and are optimistic about the opportunities ahead.

Blair Jackson:

In 2023, we successfully executed our strategy to position the business for sustained profitability and growth. Our financial results for 2023 reflect a number of one-time factors, such as back payments and reinstatement of the long-acting INVEGA royalties, one-time legal expenses associated with the Janssen arbitration and the settlement of the VIVITROL patent matter, and most notably the separation of the oncology business, which had operational financial and tax consequences. As a result of the completion of the separation in November, oncology related expenses incurred during the year qualify as discontinued operations. Expenses and our bottom-line results inclusive of these discontinued operations are fully outlined in our press release issued this morning.

That said, today I'll focus on continuing operations as those results are more relevant to the financial profile of the company going forward. Across the business, in 2023, we worked to streamline and position the company for future growth. With the moving pieces I mentioned now behind us, we have clarified and strengthened the financial profile of the business and we believe we are well positioned to execute on our strategy as a pure-play neuroscience company. Over the next few minutes, I'll take you through the details of our 2023 results, then turn to our 2024 financial expectations.

Our 2023 financial results reflect strong performance of our core neuroscience business. We generated total revenues of nearly $1.7 billion, driven primarily by our proprietary product portfolio which grew 18% year-over-year. From a bottom-line perspective, we recorded GAAP net income of $355.8 million, compared to a GAAP net loss of $158.3 million in the prior year, and non-GAAP net income of $243.7 million, compared to $57.9 million in 2022.

Turning to our proprietary products. For the year, we recorded VIVITROL net sales of $400.4 million, reflecting 6% growth year-over-year. Net sales of the ARISTADA product family increased 8% to $327.7 million in 2023, driven by unit growth; and LYBALVI net sales increased 100% year-over-year to $191.9 million.

Moving on to our manufacturing and royalty business. For the year, we recorded manufacturing and royalty revenues of $743.4 million, compared to $332.0 million in the prior year. Revenues from the long-acting INVEGA products were $486.1 million, compared to $115.7 million in the prior year, reflecting the reinstatement, and back payment of royalties, related to these products in 2023. Revenues from VUMERITY were $129.3 million, compared to $115.5 million in the prior year.

Turning to expenses for full year 2023. Costs of goods sold related to continuing operations were $253.0 million, reflecting a year-over-year increase of approximately $35 million driven by the increase in net sales of proprietary products.

R&D expenses related to continuing operations were $270.8 million, and flat year-over-year, reflecting focused investments in our neuroscience development programs, including the ALKS 2680 clinical program and support activities for our proprietary products.

SG&A expenses related to continuing operations were $689.8 million in 2023. The increase of $99.0 million as compared to the prior year was primarily related to investment in the launch of LYBALVI and non-recurring legal expenses.

During the year, we recorded a net tax benefit of $97.6 million, driven primarily by the partial release of a valuation allowance related to our Irish net operating loss carryforwards in the fourth quarter. This is a one-time adjustment due to the separation of the oncology business and our expectation of sustained profitability going forward. More detail can be found in our press release issued this morning.

During the year, we undertook significant work to streamline our operations and enhance the growth and profitability of the business going forward. While this work was underway, we continued our focus on operational efficiency and generated strong profitability and cash flows with GAAP net income from continuing operations of $519.2 million, non-GAAP net income from continuing operations of $396.5 million and EBITDA from continuing operations of $486.3 million.

Turning to our balance sheet, we ended the year in a strong financial position with $813.4 million in cash and total investments and with total debt outstanding of approximately $290

million. Looking ahead, we expect the business to continue to generate significant cash flow. In addition, upon the closing of the sale of our Athlone, Ireland manufacturing facility to Novo Nordisk expected later this year, Alkermes will be entitled to a one-time cash payment of $92.5 million for the facility and related assets, subject to customary adjustments in accordance with the purchase agreement.

I'll shift now to our financial expectations for 2024. These expectations were outlined in the press release and 8-K issued this morning.

Starting with the topline, we expect total revenues for 2024 to be in the range of $1.5 to $1.6 billion and expect net sales from our proprietary products to exceed $1 billion, reflecting continued growth of our proprietary products, led by LYBALVI. Our total revenue expectations for the year also reflect the previously disclosed expiration of the royalty related to U.S. sales of one-month INVEGA SUSTENNA in August of 2024.

In terms of expenses, our expectations for 2024 reflect reduced spend across all line items due to the separation of the oncology business, other 2023 non-recurrent expenses and our continued focus on efficiency and profitability.

Costs of goods sold are expected to be in the range of $230 to $250 million.

R&D expenses are expected to be in the range of $225 to $255 million, reflecting a decrease of approximately $150 million compared to 2023 as a result of the separation of the oncology

business. This level of R&D spend accommodates initiation of the ALKS 2680 phase 2 program in narcolepsy, as well as preclinical work to advance additional orexin compounds in other disease areas, and support activities for our portfolio of proprietary products.

SG&A expenses are expected to be in the range of $625 to $655 million, reflecting investments in the launch of LYBALVI and appropriate levels of support for VIVITROL and ARISTADA.

With our enhanced profitability profile, we expect an effective tax rate of approximately 17% in 2024.

We expect GAAP net income to be in the range of $350 to $390 million, EBITDA in the range of $445 to $485 million and non-GAAP net income in the range of $465 to $505 million.

With a proprietary product topline that is expected to exceed $1 billion this year, a sharpened strategic focus, and an operating structure that we have carefully calibrated to support the needs of the business going forward, we believe we have positioned the company for significant growth and profitability.

Richard Pops:

Alkermes now joins a small group of biopharmaceutical companies that have successfully developed and secured regulatory approval for novel medicines, effectively commercialized

them and generated significant profitability and cash flow. With that distinction, our capital allocation strategy takes on new importance.

Our capital allocation decisions are guided by a framework designed to drive near and long-term growth. It starts with focus. Alkermes is now a pure-play neuroscience company, with demonstrable and leverageable commercial and scientific expertise.

Our first priority is to maximize the potential of our current commercial products, with the most intense investment currently deployed to support the growth of LYBALVI. These investments are designed to drive growth over the near and medium term.

Second, we will invest in our pipeline to develop and advance new neuroscience candidates that can drive significant value, including ALKS 2680 and additional earlier-stage programs. Investments in R&D are made with discipline and rigor, and with predefined stage-gates and success criteria for each program, with an emphasis on early translational clinical data.

Third, beyond our internal efforts, we will explore external opportunities to expand our portfolio with assets that are a strong strategic fit. In these efforts, we plan to prioritize commercial assets that leverage our infrastructure and capabilities as well as development candidates that align with our expertise and fit within our core neuroscience focus.

And the fourth element of our capital allocation strategy is to prudently return excess capital beyond our organic and inorganic growth needs to our shareholders. As Blair mentioned, looking

ahead, we expect the business to continue to generate significant cash flow. This week, our Board of Directors approved a share repurchase program for up to $400 million, which we plan to deploy opportunistically over the next several years.

With the significant work and accomplishments of 2023 behind us, we now set our sights on building the company for the future. Augmenting the pipeline will be a key strategic priority for the business this year. We gravitate toward development programs that align with our expertise and where there is a strong biological rationale, challenging molecular design, a clear clinical pathway with early proof-of-concept, and, importantly in this intense payer environment, the potential to significantly advance the standard of care.

ALKS 2680 represents one such opportunity. The data in patients with narcolepsy type 1 from our phase 1b study were compelling and supported acceleration of the program into phase 2. Study start-up activities are underway, and we are on track to initiate next quarter.

For narcolepsy type 2 and idiopathic hypersomnia, we are in the process of completing enrollment of the phase 1b study cohorts. Data from these cohorts will inform dose selection for a potential phase 2 study. The phase 2 program for ALKS 2680 will be conducted at multiple sites around the world and we are working to initiate them as quickly as possible.

2024 is set to be an exciting and important year, enabled by the significant work over the last several years to reposition the company. We look forward to updating you on our progress and appreciate the continued support of our shareholders.