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14 Feb 2024 | **News**

Sage Sees New Diagnosis Trend In PPD As Zurzuvae Launch Gets Off The Ground

by Jessica Merrill

It's early days in the launch of Zurzuvae for postpartum depression, but Sage highlighted encouraging prescription trends during the company's fourth quarter sales and earnings call.

Sage Therapeutics, Inc.'s new postpartum depression (PPD) drug Zurzuvae (zuranolone), has only been available to patients since mid-December so there is limited data by which to measure the launch, but chief business officer Chris Benecchi said the company is encouraged by early prescription trends during the company's fourth quarter sales and earnings call on 14 February.

Zurzuvae is Sage's primary growth driver following its approval by the US Food and Drug Administration last year, but treating and diagnosing postpartum depression is a challenging area despite unmet need. Sage shares costs and sales for Zurzuvae with its partner *Biogen, Inc.*.

Benecchi said the company has seen two early shifts in prescribing and diagnosis of PPD since Zurzuvae became available, however, and noted that both are encouraging trends. One is that prescriptions are coming from psychiatrists and OB/GYNs at nearly an equal rate, as well as from a few primary care doctors. The other is that PPD is being diagnosed faster by clinicians rather than clinicians referring patients to a

Key Takeaways

- Sage has seen new postpartum depression treatment trends following the launch of Zurzuvae in that clinicians are diagnosing and treating patients faster.
- The company said it has not seen any substantial reimbursement headwinds for Zurzuvae yet but that coverage policies are still being developed.
- Sage benefited in the fourth quarter from a $75m milestone payment from Biogen related to the first commercial sale of Zurzuvae.

specialist.

Altogether, 120 prescriptions were written for Zurzuvae in the roughly 10 days it was available in December, the company reported.

“What I think we’re seeing here is a paradigm shift,” Benecchi said. “Historically, what’s happened in the diagnosis and treatment of PPD is clinicians have suspected and then they’ve referred out. What we’re actually seeing here are clinicians, the clinicians that we’re calling on … diagnosing and treating, which is very different than what we’ve historically seen.”

Prescriptions have continued to increase in early 2024, Benecchi added.

Biogen reported net sales of Zurzuvae of under $2m from the December launch through the end of the year one day earlier. (Also see "*Flat Is The New Up As Biogen Anticipates Stabilizing Product Revenue In 2024*" - Scrip, 13 Feb, 2024.) Sage receives 50% of net Zurzuvae revenue recorded by Biogen and collected $824,000 in collaboration revenue during the fourth quarter. Net revenues are recorded when Biogen ships Zurzuvae to distributors and are not based on the number of prescriptions delivered from specialty pharmacies to patients, the company pointed out. The initial revenues represent efforts to prepare the channel for the launch in the fourth quarter, Sage added.

As for reimbursement, Benecchi said conversations with payers over reimbursement are ongoing. “The vast majority of shipped prescriptions are being covered by payers, even as coverage policies are being developed,” he said. “We are, so far, not encountering significant payer headwinds, and to the contrary, we are seeing positive payer engagement.”

Both Sage and Biogen could use a strong new growth driver, but investors have cautious expectations for the launch of Zurzuvae, especially after the launch of Sage’s first drug for PPD, Zulresso (brexanolone) in 2019 never really got off the ground. Zulresso has particularly challenging commercial dynamics in that it is administered by I.V. over 60 hours and requires constant inpatient monitoring. Zulresso only generated $2m in the fourth quarter, despite many years on the market.

Zurzuvae is given orally over a 14-day course of treatment, but it does carry warnings on the risk of CNS depressive effects, including somnolence, confusion and driving impairment. Sage and Biogen had hoped to receive approval of the drug for major depressive disorder in addition to PPD but FDA requested another trial before granting the broader approval.

After the setback, Sage announced it would cut jobs and R&D programs to rein in spending. (Also

see "*Sage Details 40% Job Cuts While Zurzuvae's Future In MDD Remains Unclear*" - Scrip, 31 Aug, 2023.)

Sage benefited financially in the fourth quarter from the launch of Zurzuvae beyond product sales, as Biogen paid its partner a $75m milestone fee related to the first commercial sale. However, Sage reported a net loss of $32.7m for the fourth quarter and a net loss of $541.5m for the year. The company had $753.2m in cash of 31 December, enough to fund operations into 2026.

Sage did not update investors on its future plans for Zurzuvae in MDD and whether or not the company will continue to pursue the indication, though management has previously said the focus will remain on PPD for now.

The company has several important data readouts expected this year, including the results of a Phase IIb study of Biogen-partnered SAGE-324 in essential tremor and data from several Phase II studies testing a positive allosteric modulator of the NMDA receptor, dalzanemdor, in mild cognitive impairment (MCI), including in patients with Parkinson's disease, Huntington's disease and Alzheimer's disease. Sage CEO Barry Greene and chief scientific officer Mike Quirk talked to *Scrip* about the various data catalysts in an interview at the J.P. Morgan Healthcare Conference in January. (Also see "*Sage Ready To Turn Over Cards On Bets Outside Of Depression*" - Scrip, 12 Feb, 2024.)