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Idorsia, Still Facing Cash Crunch, Says Cost-Reduction Effort Will Conclude In 2023

by Joseph Haas

With a commercial product ramping up in the US and EU and three Phase III candidates, Idorsia is burning through cash quickly and needs more remedies beyond its 475-person headcount reduction.

Idorsia Ltd. said the cost-reduction initiative it unveiled in July will be complete by the end of 2023 and ultimately about 475 positions will be eliminated, a combination of about 300 staff cuts mostly in research and development as well as attrition and cancellation of job openings. During its nine-month financial review on 24 October, the Swiss specialty pharma said its cash will last only into early 2024 and it is looking into a variety of possibilities to extend its runway.

Year-to-date sales of its insomnia drug Quviviq (daridorexant) totaled CHF20m (about $22.4m), which was considered a disappointment across the board by analysts who speculated that Idorsia may need to sell the drug as well as the hypertension candidate aprocitentan, which it reacquired full rights to in September from *Johnson & Johnson*, and other pipeline assets. (Also see "*Johnson & Johnson Gets Its Aprocitentan Money Back*" - Scrip, 6 Sep, 2023.)

Idorsia Makes Progress With Quviviq, But Needs Cash To Fund Big R&D And Launch Spending

By Andrew McConaghie

10 Jul 2023
Idorsia has a serious cashflow problem because of major R&D and drug launch commitments, but is banking on its blockbuster bets coming good, including two potential first-in-class cardiovascular drugs.

Read the full article here

Under review at both the US Food and Drug Administration and the European Medicines Agency, the US action date for aprocitentan has been moved back three months to 19 March, the company said. The drug, which could become the first dual endothelin-1 antagonist approved for hypertension, hit Phase III

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endpoints for resistant hypertension in data reported out in November 2022. (Also see "*Idorsia/J&J's Aprocitentan Hits Phase III Mark, Could Become First ET-1 Antagonist For Hypertension*" - Scrip, 9 Nov, 2022.)

Idorsia attempted to paint an optimistic picture, however, noting that sales of Quviviq in the US are transitioning to commercial product, the drug has been added to the *CVS Caremark* formulary and work is ongoing to get the drug covered by Medicare starting in 2024. In addition, CEO Jean-Paul Clozel told a same-day call that the firm reduced its estimated operating loss for 2023 to CHF670m (about $750m) from the previous CHF735m (about $823m). (Also see "*Finance Watch: UroGen Accesses Cash After Phase III Bladder Cancer Success*" - Scrip, 28 Jul, 2023.)

Key Takeaways

- Three months after announcing a staff cut and a goal to cut expenses by 50%, Idorsia still faces an immediate need for cash to fund the launch of Quviviq and a significant late-stage pipeline.
- The launch of insomnia drug Quviviq remained sluggish, with the drug bringing in CHF8.4m during Q3, despite positive trends in the US and new EU launches.
- Analysts warn that Idorsia will need an equity raise and divestment of multiple drugs just to get enough cash to last beyond mid-2024.

In addition, the July deal to sell off its Asia-Pacific business – except for China – to *Sosei Heptares* brought in CHF400m ($466m) while reducing the overhead of its commercial and R&D operations in Japan and South Korea. ({A#SC148732]) Clozel conceded that with the sell-off of the APAC business, Idorsia is suspending its previous goal to achieve profitability by 2025.

All of those measures combined, said chief financial officer Andre Muller, still leave Idorsia with a "short-term priority" to extend cash runway, which might include several out-licensing transactions he described as "balls in the air that we expect to catch in the upcoming months."

Despite the cost-reduction initiative, which Idorsia said in July was intended to reduce spend by 50%, analysts say the company has a lot of work to do to approach financial solvency. Kepler Cheuvreux analyst Justine Telliez said sales of Quviviq during Q3 of CHF8.4m (about $9.4m) missed her firm's projection of CHF9.8m and consensus estimates of CHF9.9m.

"To date, there is no significant shift in the sales trajectory," Telliez said, while noting the company's optimism. The drug, launched in 2022, is now on formulary with two of the largest commercial insurers in the US, CVS and *Express Scripts Holding Company*, and Idorsia expects coverage under Medicare in Q1 2024, according to Clozel. (Also see "*Idorsia In Dreamland With*

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Insomnia Drug Approval" - Scrip, 10 Jan, 2022.) In addition, the dual orexin receptor antagonist is now launched in four of the five largest EU markets following a September rollout in Spain and a UK introduction this month.

In the US, Idorsia is gradually moving Quviviq from a copay model meant to drive uptake and demand to commercial sales, with 48% of prescriptions in Q3 under the commercial model, up 11% from Q2, Clozel said. Octavian analyst Laura Pfeifer-Rossi said in a 24 October note that September prescription trends showed a further increase to 57% of prescriptions written for commercial product. Prescription volume is now growing slowly in the US, the company added.

Financing Plus Divestments Needed, Analysts Urge

Telliez said Idorsia needs an immediate cash infusion and predicted a dilutive stock sale that might bring in CHF150m (about $168m), but that still would give the company runway only into mid-2024.

“One option to find cash could be to license or sell its main products, aprocitentan and/or Quviviq, which might provide significant upfront payments,” the analyst suggested. “Another potential strategy could be licensing its Phase III assets, selatogrel and/or cenerimod. While these deals may offer limited upfront payments, they could play a key role in substantially decreasing the company’s ongoing cash burn.”

Selatogrel is a reversible P2Y12 receptor antagonist in Phase III for secondary prevention of heart attacks. (Also see "*An EpiPen For Heart Attacks? Idorsia Launches Phase III Study Of Selatogrel*" - Scrip, 19 Aug, 2021.) The self-injectable drug has been described as an “EpiPen for heart attacks,” but is in a Phase III outcomes study that is not expected to yield data until 2025, therefore offering no near-term inflection point for Idorsia other than the revenue it could generate from divesting the candidate.

Cenerimod (ACT-334441), a follow-on to J&J’s multiple sclerosis drug Ponvory (ponesimod), is a sphingosine-1-phosphate receptor 1 (S1P1) modulator in Phase III for systemic lupus erythematosus. The Phase III OPUS-1 and OPUS-2 studies are testing the drug as add-on to standard-of-care SLE therapy and were initiated last December, according to Biomedtracker.

Jefferies analyst Brian Balchin offered a similar glum assessment for Idorsia in a 24 October note, basically suggesting that the company could sell itself off in pieces to gain financial runway for whatever would be left. A CHF140m ($157m) equity raise could enable the company to continue operations into Q2 2024, at which point it could generate CHF650m ($728m) by selling off aprocitentan for CHF200m, Quviviq for CHF350m and selatogrel for CHF80m.

Balchin called this a best-case scenario that would give Idorsia runway until August 2025, albeit for a company built entirely around cenerimod, potential earnouts from the sold-off products

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and its earlier-stage pipeline.

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