BofA SECURITIES

US Biopharmaceuticals

What caught our attention in SF (Day 3): ALKS, AMPH, HRMY, IONS, VTRS

Industry Overview

We flag company updates from a competitor healthcare conference with a focus on updates that represent 'new messaging', shifts in investment narratives and/or warrant further interrogation. The note continues on page 2.

AMPH: pipeline updates, '23 commercial outlook

In a fireside chat, Amphastar offered some pipeline updates and commentary on performance of key business units. On pipeline, the company formally disclosed AMP-018 is a GLP-1 generic with greater than $2bn IQVIA sales which would suggest once-daily Victoza. Amphastar plans to file its Gx GLP1 sometime in 2024. The company also fine-tuned FDA action dates for its two metered dose inhaler programs AMP-008 and AMP-007 in 2Q24 and 4Q24 respectively. On the commercial front, Baqsimi US sales for FY23 are coming in closer to $150-155m (within broader $145-155m range), though AMPH only books 2H profits pending transfer of product distribution in 1Q24. In the fireside, management indicated it will deliberately ramp up its contracted sales force effort with a focus on managing profitability while ramp to Baqsimi peak target of $250-275m is expected to take more than 5 years (in-line with our forecast). With regards to US generic pricing, management believes that it has a high barrier to entry portfolio that is more immune to price competition than peers. On the call, no near-term supply swings called out (good or bad). M&A remains one of the company's strategies but mgmt framed a high bar for potential acquisition targets.

VTRS: focus on capital deployment

Viatris' was a notable outperformer (+5% vs +1% DRG), presumably on management commentary on capital deployment. In our view, management's comments around 2024 free cash flow (~$2.3bn excluding one-time costs) and guard-rails (50% allocated to dividend/buybacks) were reiterations of past messaging, though it is our sense some investors had concerns around the company honoring those commitments following recent management changes (at CFO position). Of note, management indicated it would be "aggressive" on buybacks in 2024-25 which was a slight tone shift. On the business, management 1) reiterated its outlook around low-SD revenue growth but flagged Japan (JANZ) as a market that could see Y/Y decline until 2026; 2) gross margins expected to be stable in 2024. Management commentary on M&A consistent with prior comments around TA focus and seemed to skew towards more licensing and partnership type deals. While the company does not have a bias towards regions, CEO noted that companies which do not have line of sight to commercialize in ex-US may be a good fit given strong EU commercial infrastructure. On the recently acquired Tyrvaya (acquired through Oyster Point), management talked about product transition, integration and need for DTC campaign to drive a more meaningful growth inflection.

Continued on page 2: ALKS, HRMY, IONS

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Acronyms:
FDA: food & drug administration
GTN: gross-to-net deductions
NT1, NT2: narcolepsy type-1 / type-2
IH: idiopathic hypersomnia
MAD: multi-ascending dose
HV: healthy volunteers
AE: adverse event
CMS: Centers for Medicare & Medicaid Services
TBD: to be determined
DTC: direct to consumer
Gx: generic
TA: therapy area

ALKS: orexin updates + Lybalvi outlook in 2024E

Alkermes' (ALKS) fireside chat was focused on orexin (key pipeline) milestones and preliminary financial outlook in 2024E. Much of ALKS' clinical plans for its Ph1 orexin agent ALKS2680 in 2024 had been disclosed in recently issued 8-K slides (see our Jan 8, 2024, report for initial takeaways), but incrementally we note that ALKS plans to present full Ph1 data in NT1 either at Sleep (summer) or World Sleep (fall), whereas timing for Ph1 update in NT2/IH (expected in 1H24) does not seem imminent to us given NT2/IH cohorts are still enrolling patients. In NT2/IH cohorts, ALKS plans to interrogate dose range 2-3x higher than NT1, which would imply (to us) a dose range up to ~24mg. While ALKS has explored dose up to 25mg in Ph1 MAD in HV, we have little visibility to the safety profile of '2680 at higher dose range (no AE table presented) and propensity for visual disturbance AE remains TBD in NT2/IH (not orexin-deficient). On Lybalvi (mood disorders), DTC impact and evolution of GTN remain areas of focus. Management indicated they are seeing initial impact from DTC on recent Lybalvi script trends and sales mix remains fairly split between schizophrenia and bipolar. ALKS expects Lybalvi GTN to remain stable in 1H24 (vs 26-27% in '23) but GTN may widen if they choose to expand commercial contracting in 2H24 (vs over 75% reimbursement from CMS). Lastly on capital allocation, ALKS contemplates returning capital to shareholders (eg share repurchase) at the Board level and plans to provide an update later this year.

IONS: framing catalyst-rich 2024, refined data timing

Ionis' (IONS) fireside chat was focused on the recently approved Wainua and the company's late-stage pipeline. Overall, IONS' messaging and strategy on Wainua for polyneuropathy (PN) and cardiomyopathy (CM) remains unchanged vs our recent Bus Tour discussions with management (see our Dec 11 report for takeaways). Earlier this week, IONS refined timing a couple of clinical data readouts (donidalorsen HAE Ph3 in 1Q24 vs 1H24 prior, olezarsen sHTG Ph3 in 2025 vs late'24/early'25 prior) which were largely in-line with our expectations given enrollment timeline communicated prior. Other pipeline commentary of note include: 1) donidalorsen – ahead of Ph3 topline in 1Q, IONS framed focus is on showing a competitive efficacy profile with differentiation on (less frequent) dosing regimen, 2) olezarsen for sHTG – IONS suspects enrollment may complete 1Q24, which would position Ph3 for a topline readout in 1H25 given one-year study duration (vs current guidance of 2025 readout), 3) broader pipeline – no meaningful updates, which is not a surprise given IONS provided a substantial R&D Day update a couple of months ago.

Acronyms: HAE: hereditary angioedema, sHTG: severe hypertriglyceridemia

HRMY: '24 guidance and expected pipeline updates

Following yesterday's PR pre-announcing FY23 Wakix revenue of $582m (+33% Y/Y; +350 patients Q/Q) in-line with cons and FY24E revenue guidance of $700-720m (vs. cons $708m), management focused its discussion on Wakix (pitolisant) lifecycle management updates expected in 2024. On LCM programs, management reiterated planned data disclosures for its two next-generation pitolisant formulations in 1H24. Management framed the "real opportunity" coming from its enhanced formulation which will allow for higher dosage, optimized PK and longer-duration patent protection (defined 2040+). Time-to-market for the enhanced formulation is towards the end of the Wakix life cycle, which could range 2027-30 depending on how the patents hold up to challenge. In the fireside, management was more specific about possible indications for the enhanced pitolisant formulation possibly for DM1 and other forms of narcolepsy. With regards to the recently failed Wakix Ph3 IH study, management will provide an update on its 1Q24 earnings call following meeting with FDA. Based on management's commentary, we expect management to argue 'totality of data' and safety/tolerability trade-offs versus the only approved IH treatment (Xywav). However, we continue to believe another pivotal study will be required for approval given first study failed to show statistical sig on primary endpoint vs. management "optimistic for constructive dialogue" on a path forward.

Acronyms: PR: press release; LCM: lifecycle management; PK: pharmacokinetic; DM1: myotonic dystrophy type 1; IH: idiopathic hypersomnia; FDA: Food & Drug Administration

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