First Take

Ocuphire Pharma, Inc. (OCUP)

November 8, 2022

Price: $2.09; Market Cap (M): $43; *11/7/2022 Close*

Rating: Buy; Price Target: $26.00

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Nyxol Global License Agreement Paves Refractive Path Forward

Strategically moving pieces to align novel ophthalmology platform. We highlight that Ocuphire's announced global license agreement for development and commercialization of its lead small molecule eye drop candidate Nyxol reflects one aspect of several positive strategic moves involving not only Ocuphire, but global healthcare company Viatris Inc. (VTRS; not rated), Famy Life Sciences (private), and Oyster Point Pharma (OYST; Buy; Caufield). At a high level, we note the announcement of Ocuphire's exclusive development and commercialization license agreement with Famy directly coincides with Viatris' announced acquisition of both: (1) Famy Life Sciences; and (2) Oyster Point Pharma, essentially bringing both the development and commercialization plans for Nyxol along with Oyster Point's commercial dry eye disease (DED) nasal spray product Tyrvaya and its ocular surface disease platform under the umbrella of Viatris, with the announced acquisitions expected to close 1Q23. With that said, we believe it is important to convey that the triangle of strategic alignments around the licensing agreement for Nyxol were part of this plan from early onset, from our understanding, with Ocuphire onboard with Viatris establishing its novel ophthalmology and licensing franchise to facilitate Nyxol's path forward and based on the announced acquisitions. More specifically, we note Viatris includes the licensed development for Nyxol within the strategic update of its new ophthalmology portfolio pipeline, represented by respective development related to mydriasis (MR-140), presbyopia (MR-141), and dim light or night vision disturbances (NVD) (MR-142). We believe the biggest takeaway is that nonselective alpha-1 and alpha-2 adrenergic antagonist Nyxol is in capable hands that bring broad indication experience for the next stages of developmental and commercial advancement, from our perspective.

Leveraging boots on the ground for prospective RM approval. With anticipated NDA submission 4Q22 for Nyxol in the reversal of mydriasis (RM), we remind investors that Nyxol as a cash-pay pupil dilation reversal agent is independent of reimbursement and could be launched as early as 2023, pending approval. In terms of how FDA approval in RM would benefit from the aforementioned acquisitions and strategic alignment, we highlight Oyster Point's product Tyrvaya is already being marketed and sold in DED, with that established U.S. commercial sales force serving as the prospective foundation for commercial launch of Nyxol in RM, across ophthalmologist and optometrist practices. Admittedly, we would not have anticipated a prospective scenario where the Tyrvaya commercial sales force was also representing Nyxol in the treatment of RM, although we receptively welcome the nuanced strategic development as a viable path towards Nyxol commercial advancement, with approval. We here draw on feedback from both the ophthalmologist and optometrist perspectives discussed during our 2nd Annual Ophthalmology Conference, where reception to the utilization of candidate Nyxol, if approved, was expected to be strong as a novel eye drop therapy not only in RM during routine dilation, but prospectively within the treatment of presbyopia as well as NVD. Moreover, beyond Nyxol's potential for domestic commercialization, we note the license agreement with Famy defines the development and commercialization of Nyxol across three indications, particularly RM, presbyopia, and NVD, in the US, Europe, Japan, India, China, and additional global markets. We believe this latter commercial point resonates particularly regarding Viatris' plans to commercialize Nyxol pending respective regulatory approvals, while leveraging its global commercial infrastructure.

Not the odd man out—APX3330 poised for differentiation. In addressing financing needs with the announced $35M upfront payment, development funding and milestones with tiered double-digit royalties to Ocuphire facilitating refractive pipeline development and the APX3330 retinal program, we specifically remind investors that oral therapy APX3330, for the treatment of diabetic retinopathy (DR) patients, is not only unique from Nyxol mechanistically, but is specifically separate from the development and commercialization license agreement. We therefore believe APX3330 can remain an internal focus for Ocuphire, with forthcoming plans for reporting top-line results early 2023 from the Phase 2b ZETA-1 trial of oral therapy APX3330 in the treatment of diabetic retinopathy patients.

We continue to anticipate potential improvement in Diabetic Retinopathy Severity Score (DRSS), being evaluated to 24 weeks (≥2-step improvement in DRSS in study eye), with APX3330 intended to address both angiogenesis and inflammation through inhibition of transcription factor regulator Ref-1. We underscore this MOA is designed to both: (1) block activation of HIF-1α impacting the VEGF signaling cascade as an anti-VEGF effect; and (2) reduce activation of NF-kB impacting chemokines and other downstream growth factors involved in the inflammatory cascade as an anti-inflammatory effect. With APX3330 reflecting a potential oral therapy in DR/DME, we maintain our view that APX3330 does not need to directly compete with anti-VEGF on efficacy. We believe that with 15-20% of patients demonstrating ≥2-step improvement in DRSS score, this could be viewed positively with APX3330 acting as a complimentary therapy to anti-VEGF, or potentially providing oral therapy optionality compared to commencing burdensome anti-VEGF intravitreal injections.

Valuation and risks. We reiterate our Buy rating and $26 price target. Our price target of $26 per share is based on an equally-weighted composite of: (a) $34.18 per share, as a 25x multiple of taxed and diluted 2030 EPS of $3.63 discounted back to December 2022 at 13%; and (b) an NPV discounted cash flow between 2022-2030 of $17.36 per share, with a discount rate of 13% and growth rate of 1%. These assumptions are in-line with the expected P/E multiple and discount rates of an early developmental-stage biopharmaceutical company. Risks to our investment thesis and target price include: (1) failure of developmental candidates to achieve peak commercial revenue estimates in our model (due to market size, penetration rates, and/or pricing); (2) failure to secure capital resources to fund operations; and (3) continued program development and commercialization.

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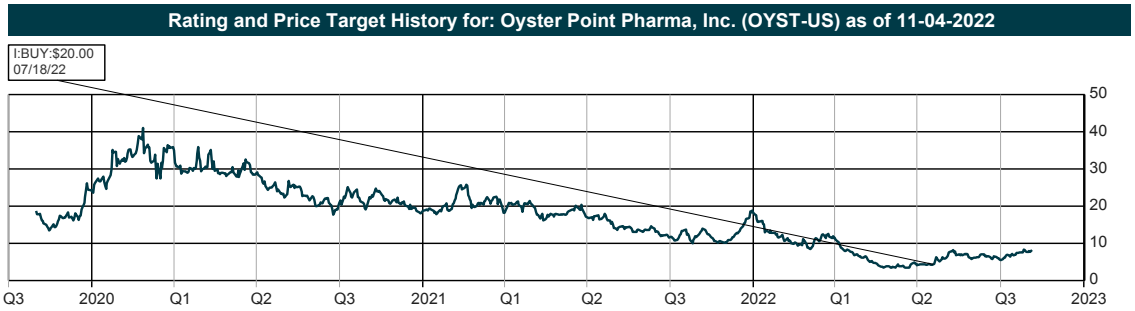

Related Companies Mentioned in this Report as of Nov/07/2022

Company	Ticker	H.C. Wainwright Rating	12 Month Price Target	Price	Market Cap
Oyster Point Pharma, Inc.	OYST	Buy	$20.00	$11.57	$310

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			IB Service/Past 12 Months	
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Under Review	14	2.14%	3	21.43%

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