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#### (NASDAQ: OCUP)

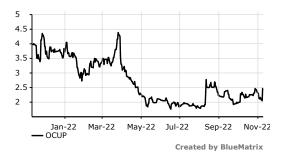
Price	\$2.49
52 Week Range	(\$1.78 - \$5.50)
Price Target	\$25.00
Market Cap (mil)	\$49.00
Shares out (mil)	20.81
3-Mo Avg Vol	83,972
Cash per share	\$2.35
Total Debt (mil)	NA
Debt/Equity	NA

Cash per share: Pro forma cash/share following recent Famy/ Viatris milestone

Revenues (thousands) \$										
Yr Dec	2021A	202	22E	202	23E					
	Actual	Curr	Prev	Curr	Prev					
Mar	-	-	-	4E	-					
Jun	-	-	-	4E	-					
Sep	-	-	-	4E	-					
Dec	-	-	-	4E	-					
YEAR	1A	-	-	16E	-					

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EPS \$					
Yr Dec	2021A	202	22E	202	23E
	Actual	Curr	Prev	Curr	Prev
Mar	(0.47)A	(0.35)A	-	(0.18)E	(0.36)E
Jun	(0.52)A	(0.25)A	-	(0.19)E	(0.35)E
Sep	(0.25)A	(0.22)A	(0.26)E	(0.19)E	(0.36)E
Dec	(0.35)A	(0.28)E	(0.29)E	(0.20)E	(0.38)E
YEAR	(1.54)A	(1.10)E	(1.15)E	(0.75)E	(1.45)E



# **Ocuphire Pharma, Inc.**

# Buy

#### Estimate Change

Volatility: 5

# FamyGen/Viatris partnership a signficant positive for OCUP and the expected launch of Nyxol too

OCUP recently announced their 3Q22 results highlighting and more importantly just yesterday morning the company held a call to announce the significant development and marketing partnership for Nyxol with FamyGen Life Sciences (Famy), which itself was also acquired by Viatris (VTRS, NR), a multi-national pharma company that will oversee the launches of Famy's newly acquired assets. The Famy deal brings in \$35M in up-front milestones, covers all future development, regulatory, and sales expenses for Nyxol plus up to an additional \$130M in (undisclosed) sales milestones, and a tiered double-digit sales royalty. The agreement covers Nyxol across all three of its indications: the reversal of mydriasis (RM), presbyopia, and night vision disturbances (NVD). This deal is really a wonderful deal for OCUP, in our opinion, and one that reflects the value that the Nyxol franchise brings to OCUP. Interestingly APX3330 was not included in the current deal, but it would seem most likely that VTRS is keeping a close eye on APX3330 as well, and should there be positive data from this ongoing Phase 2b trial (data expected 1H23) we believe an additional deal could be struck, if not the outright acquisition of OCUP altogether. OCUP is currently conducting pre-commercial activities for Nyxol, including planning a New Drug Application (NDA) for this quarter, followed by a potential launch in late 2H23-1H24. We are reiterating our Buy rating and our \$25 price target based on a sum-of-the-parts, primarily based on our expectations for the company's NVD & presbyopia pipeline. We value OCUP's Nyxol for NVD at \$11/share, Nyxol & low-dose pilocarpine (LDP) for presbyopia at \$10/share, and Nyxol for RM at \$2/share. We value the remaining assets and cash (end '23E) at \$2/share for our \$25 price target.

**Global licensing agreement to cover the full development and commercialization of Nyxol.** OCUP has entered into an exclusive license agreement with FamyGen Life Sciences Inc. which entails the development of Nyxol in all of its indications across the US, Europe, Japan, India, China, and other global markets. Under the terms of the agreement, OCUP will receive an upfront payment of \$35M which should cover the pre-commercial activities of Nyxol needed for FDA approval, in addition to aiding in expediting the clinical trials set for in presbyopia and NVD. A milestone payment of \$10M is also a possibility once FDA approval of Nyxol in RM is granted, with additional milestone payments set upon the approval of Nyxol's additional indications. The commercialization of Nyxol is also covered, as Viatris Inc, a global healthcare company, has agreed to commercialize Nyxol following each regulatory approval.

Ever closer to a potential approval of Nyxol with NDA submission expected by year-end. The most recent trial of Nyxol in RM is the MIRA-4 trial, which was completed early this year and established Nyxol's efficacy in reversing mydriasis in the 23 pediatric patients (aged 3-17) studied. Specifically, this trial showed that 64% of patients were able to return to baseline pupil diameter (PD) at 90 minutes after dilation, compared to solely 25% of placebo patients, all with no adverse events reported. This trial marks the gathering of the full dataset from all the MIRA trials which further showcase Nyxol's ability to significantly have treated patients return to  $\leq 0.2$  mm of their baseline PD at 90 minutes after dilation. With these positive findings, the company plans to submit an NDA with the full MIRA dataset by the end of the year, followed by a possible approval and launch in late 2023-early 2024.

**Nyxol + LDP to be studied in upcoming VEGA presbyopia trials.** Expanding the potential indications for Nyxol, OCUP is studying this candidate alone and in combination with 04% low-dose pilocarpine (LDP) as adjunctive therapy in presbyopia patients. The Phase 3 VEGA-2 is planned to be initiated this quarter, followed by a subsequent Phase 3 VEGA-3 trial and the 1-year safety LYRA-1 trial, both of which are planned to begin in 2023.

Recent KOL event highlights the potential for APX3330 as an oral treatment for DR/DME; ZETA-1 results in 1H23. A KOL event on oral APX3330 for DR/DME was held last month, with Dr. Peter Kaiser, Dr. Caroline Baumal, and Dr. David Lally in attendance. The KOLs highlighted the very real need for new treatment options needed in the DR/DME space as the current standard of care includes anti-vascular endothelial growth factor (VEGF) injections into the eye, though effective, are highly disliked by patients due to their mode of administration, leading to a majority of patients forgoing treatment altogether. OCUP is researching their APX3330 candidate, which works by blocking reduction-oxidation effector factor 1 (Ref-1), in turn lessening neovascularization and restoring vision. OCUP may serve as a potential alternative to anti-VEGF injections as its mode of administration is an oral tablet, making it vastly less invasive which should aid in patient compliance in obtaining ongoing treatment for their diagnosis. APX3330 is also being studied in the Phase 2b ZETA-1 trial in 103 DR patients, with topline results expected in early 2023.

**Maintain Buy rating, \$25 price target.** Our price target is based on a sum-of-the-parts, primarily based on our expectations for the company's NVD & presbyopia pipeline. We value OCUP's Nyxol for NVD at \$11/share, Nyxol & low-dose pilocarpine for presbyopia at \$10/share, and Nyxol for RM at \$2/share. We value the remaining assets and cash (end '23E) at \$2/share for our \$25 price target.

#### Valuation:

We value OCUP at \$25/share based primarily on our expectations for Nyxol for NVD and the combination of Nyxol & low-dose pilocarpine for Presbyopia, as well as Nyxol of RM. We model in that Nyxol is approved and launched for RM in 2024 and NVD in 2025 with sales reaching \$625M for NVD and \$185M for RM by year 2030. We model in OCUP receiving a 16% royalty on both. We place a 9x multiple on the royalties for both and discount each back 7 years at 15% (for NVD) and 20% (for RM) for our valuations of \$11/share for NVD and \$2/share for RM. We anticipate that the combination of Nyxol & low-dose pilocarpine for Presbyopia reaches blockbuster sales levels, and we model in this compound approved & launched in 2025 and reaching \$1.25B in sales by 2030. We model in OCUP receiving a 15% royalty on Presbyopia sales. We place a 9x multiple on these royalties discounted back 7 years at 25% for our \$10/share valuation for Presbyopia. We value OCUP's additional compounds & technology including APX3330 for DR & DME, as well as APX2009 and APX2014 (2nd generation DR & DME compounds) as well as cash (at the end of 2023E) at \$2/share for our sum-of-the-parts valuation of \$25/share.

#### Risks to achievement of target price:

**Exogenous events could impact our outlook.** We believe pharmaceutical companies have the least control over competitive, political, and regulatory risks. Although we have incorporated competitive assumptions into our forecasts, there may be other risks beyond the scope of our analysis. Changes in the drug reimbursement system, as well as any political or regulatory amendments, may significantly influence the earnings power of these companies. **Actual clinical results and the FDA's conclusions may deviate from expectations.** Many of our assumptions are based on a review of incomplete

clinical trial data available in the public domain. Often, our conclusions are drawn from early-stage data, which may not be reflected by pivotal studies. Furthermore, the FDA's conclusions may not coincide with our own, materially changing our revenue and earnings assumptions.

**Compliance issues, product recalls, and other mandates by regulatory authorities could materially change our expectations.** Regulatory compliance issues, ranging from accounting irregularities to defective manufacturing practices, could materially change our assumptions and earnings outlook. Unanticipated product recalls and labeling changes could also have adverse consequences on our earnings assumptions.

Legal risks could lead to additional liabilities and revenue loss. In addition to the expenses incurred by patent challenges, product liability and other legal suits could occur and lead to additional liabilities and revenue loss, which could substantially change our financial assumptions.

**Raising additional capital may cause dilution.** If the company requires additional funding through raises in equity offerings, or similar financial instruments shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect shareholders' rights.

**COVID-19 Impact.** If the ongoing economic & social disruption of the response to the COVID-19 virus continues that could materially impact the company's ability to conduct clinical trials or regular business.

Please see the company's SEC filings for a more comprehensive discussion of potential risks.

# Figure 1. Sum-of-the-Parts

Sum-of-the-parts valuation		
Segment	Valuation	Per share
	(000's)	value
Night Vision Disturbances	\$353,819	\$11.00
Presbyopia	\$327,166	\$10.00
Reversal of Mydriasis	\$74,736	\$2.00
Cash (end-'23E) & other tech	\$71,438	\$2.00
SUM	\$827,159	\$25.00
Fully diluted shares out '23E (00	32,761	

Source: AGP estimates

# Figure 2. Variance analysis

# Ocuphire Pharma Variance analysis

(000's)

(0003)					
	3Q21A	3Q22A	3Q22E	Variance	% Y/Y
General & Administration	1,595	1,703	2,000	(297)	7%
Research & development	3,126	2,835	3,500	(665)	-9%
Operating Income (loss)	(4,232)	(4,538)	(5,500)	962	7%
Interest inc/(exp), net	0	0	(5)	5	NM
other inc / fin expense	2	7	0	7	250%
Adj Net income	(4,230)	(4,531)	(5,505)	974	7%
Net income - as reported	0				
Wgtd Avg Shares (000)	16,925	20,498	21,003	(504)	21%
Adjusted EPS	(\$0.25)	(\$0.22)	(\$0.26)	\$0.04	-12%

Source: AGP estimates

## Figure 3: Potential clinical trial timelines

Ocuphire Pharma Branded drugs trial timelines																		
		2021	Α		2022E			2023E			2024E			2025E				
	1QA	2QA	3QA 4QA	1QA	2QA	3QA	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE 2	QE 3Q	E 4QE
MIRA-2 Nyxol for the reversal of Mydriasis (ac	ute tre	atment)	- RM															
Phase 3 MIRA-2 trial (N = 185) - POS 3/10/21	data				_													
Phase 3 #2 MIRA-3 trial (N = 368)			<b>p</b> 3	data		-												
Pediatric Phase 3 MIRA-4 trial (N = $20-30$ )				ped	data													
1 year stability on 3 batches single unit dose				stabilit	у													
NDA filing - expected 4Q22/1Q23							NDA											
FDA approval & launch										FI	DA				LAU	NCH		
LYNX-1 Nyxol for dim light, night vision distur	bances	s - NVD		Î														
Phase 3 LYNX-1 trial (N = 140)			р3		data													
Phase 3 #2 - LYNX-2 trial								р3			data							
Supplemental NDA filing												sN	DA					
FDA approval & launch																FDA	Ľ	AUNCH
VEGA-1 Nyxol & low dose (0.4%) pilocarpine	or pres	sbyopia	- P															
Phase 2 VEGA-1 trial - POSITIVE 6/30/21	p2	data							-									
VEGA-2 Phase 3 trial #1								р3		data								
VEGA-3 Phase 3 trial #2									р3		data							
Supplemental NDA filing													sN	IDA				
FDA approval & launch																FDA		AUNCH
ZETA-1 APX3330 for diabetic retinopathy & diabetic macular edema - DR					IE													
Phase 2b ZETA-1 trial in DR/DME - oral dose				p2b				data									_	
Phase 3 trial #1 - assume 2 yr trial & 2 trials													þ	03				data

Source: Company reports; AGP estimates

### Figure 4: Quarterly Income Statement

Oounhiro Dhormo											
Ocuphire Pharma											
Quarterly income statement											
		2021			2021A		202			2022E	
(\$000 except per share)	<u>1QA</u>	2QA	3QA	4QA	Year	<u>1QA</u>	2QA	3QA	4QE	Year	
Revenues											
Collaboration revenue		\$100	\$489		\$589						
Total revenues		\$100	\$489		\$589						
Expenses											
General & Administration	1,704	3,408	1,595	1,414	8,121	1,736	1,776	1,703	2,250	7,46	
Research & development	3,482	3,829	3,126	4,736	15,173	4,772	3,162	2,835	3,750	14,51	
Total operating expenses	5,186	7,237	4,721	6,150	23,294	6,508	4,938	4,538	6,000	21,98	
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Income (loss) from ops	(5,186)	(7,137)	(4,232)	(6,150)	(22,705)	(6,508)	(4,938)	(4,538)	(6,000)	(21,98	
Interest inc/(exp), net				(2)	(2)	(5)	(4)	0	(5)	(1	
other inc / fin expense	1	1	2	(161)	(157)	(82)	15	7	(0)	(6	
Adj. Net income (loss)	(5,185)	(7,136)	(4,230)	(6,313)	(22,864)	(6,595)	(4,927)	(4,531)	(6,005)	(22,05	
	(0,100)	(1,100)	(4,200)	(0,010)	(22,004)	(0,000)	(4,321)	(4,001)	(0,000)	(22,00	
Non-cash & 1x expenses	(00.000)				(00.000)						
FV change deriv liability Note extinguishment	(33,829)				(33,829)						
NI (loss) as reported	(39,014)				(56,693)						
· · ·	• · · ·										
Adj EPS	(\$0.47)	(\$0.52)	(\$0.25)	(\$0.35)	(\$1.54)	(\$0.35)	(\$0.25)	(\$0.22)	(\$0.28)	(\$1.1	
EPS as reported	(\$3.57)				(\$3.82)						
Weighted avg. shares (000)	10,924	13,609	16,925	17,855	14.853	18,888	19,503	20,498	21,248	20,0	
Fully diluted shares (000)	20,188	22,974	26,353	27,115	24,157	28,863	29,648	30,782	31,448	30,1	
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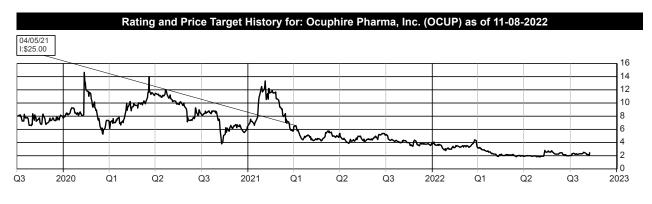
Source: Company reports; AGP estimates

#### Figure 5: Annual Income Statement

Ocuphire Pharma						
Annual income statemen (\$000 except per share)	t 2021A	2022E	2023E	2024E	2025E	Comments
Revenues						
Nyxol for RM royalties NVD royalties Presbyopia royalties				\$516	\$3,924 1,113 300	Royalties from Famy Royalties from Famy Royalties from Famy
Collaboration revenue			\$16,250	15,750	15,750	Dev. exp from Famy here
Total revenues			\$16,250	\$16,266	\$21,087	
Expenses						
General & Administration Research & development	8,121 15,173	7,465 14,519	14,000 19,250	16,500 17,000	16,500 17,000	Increasing staffing Covered by Famy
Total operating expenses	23,294	21,984	33,250	33,500	33,500	
Inc (loss) from ops	(22,705)	(21,984)	(17,000)	(17,234)	(12,413)	
Interest income	(2)	(14)	0	0	0	
other inc / fin expense	(157)	(60)	0	0	0	
Net income (loss)	(22,864)	(22,058)	(17,000)	(17,234)	(12,413)	
Non-cash & 1x expenses FV change deriv liability Note extinguishment	(33,829)					
NI (loss) as reported	(56,693)					Non-cash expenses
Adj EPS EPS as reported	(\$1.54) (\$3.82)	(\$1.10)	(\$0.75)	(\$0.70)	(\$0.45)	
Weighted avg. shares (000)	14,853	20,034	22,561	24,623	27,623	
Fully diluted shares (000)	24,157	30,185	32,761	35,123	38,123	
Cash & equivalents	\$24,534	\$43,456	\$39,448	\$26,219	\$18,061	\$35M Fami up-front 4Q22

Source: Company reports; AGP estimates

# Important Research Disclosures



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**Distribution of Ratings/IB Services** 

			IB Serv./Past 12 Mos.				
Rating	Count	Percent	Count	Percent			
BUY [BUY]	114	83.21	4	3.51			
HOLD [NEUTRAL]	16	11.68	2	12.50			
SELL [SELL]	1	0.73	0	0			
NOT RATED [NR]	6	4.38	1	16.67			
UNDER REVIEW [UR]	0	0.00	0	0			

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**Buy:** Expected to materially outperform sector average over 12 months and indicates total return of at least 10% over the next 12 months.

**Neutral:** Returns expected to be in line with sector average over 12 months and indicates total return between negative 10% and 10% over the next 12 months.

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Not Rated: We have not established a rating on the stock.

**Under Review:** The rating will be updated soon pending information disclosed from a near-term news event. **Volatility Index** 

**1 (Low):** Little to no sharp movement in stock price in a 12 month period

2 (Low to medium). Medeet ebenges in stack price in a 12 month period

2 (Low to medium): Modest changes in stock price in a 12 month period

**3 (Medium):** Average fluctuation in stock price in a 12 month period

4 (Medium to High): Higher than average changes in stock price in a 12 month period

5 (High): Extremely sharp movements in stock price in a 12 month period

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