# J.P.Morgan

# **Ophthotech**

# Our Thoughts Post the 3Q Call

Ophthotech reported a GAAP loss per share of \$10.26. On the conference call, the company reviewed the phase 3 program evaluating Fovista in combination with anti-VEGF agents for the treatment of wet AMD. Timelines for top-line data from these studies remain on track for 2016 with regulatory filing expected by YE 2016. Importantly, Ophthotech provided details on the regulatory process in EU, highlighting progress towards starting EU enrollment and CHMP buy-in on multiple aspects of the phase 3 program. That said, disclosed CHMP scientific guidance may require additional toxicology and pre-clinical work (which we believe can be addressed concurrent with the phase 3 program), and raised questions on whether the current phase 3 program will be sufficient for reviewing the drug's efficacy (details below). We believe the CHMP issue will be resolved through continued discussions/negotiations or, at worst, a bridging study, which should not delay EU approval and launch (2018, in line with our previous estimate). We continue to expect positive outcomes from the pivotal studies and forecast meaningful adoption of Fovista (~30% market share), implying a WW market opportunity of almost \$2B.

- EU regulatory update. Ophthotech cited CHMP comments regarding how the company's phase 3 program addresses dose reductions. The issue at hand is an artifact of label differences for dosing of Lucentis between Europe (PRN dosing after a 3-month lead-in) and the US (monthly dosing). Though Ophthotech argues that the appropriate time for dose reduction is after 12 months, discussions are ongoing and multiple solutions are available. One potential solution is a bridging study, and the company is prepared if needed (strong financial position: \$236M with access to \$83M from Novo A/S). Importantly, Ophthotech stressed this will not impact timelines.
- Pipeline. Fovista Recall, the first 2 of 3 phase 3 studies for Fovista in AMD have already begun. Start of the third study in combination with Avastin/Eylea is on track for 1Q14. Studies outside of naive wet AMD (e.g., anti-VEGF resistant AMD or Von Hippel-Lindau) remain on schedule for 2014 with potential data in 2015. ARC1905 Initiated process for manufacture of clinical supplies; developing protocol for clinical study set to begin in 2014.
- Adjusting estimates. Based on reported results, we are making adjustments to our model. Our 2013 GAAP EPS estimate is lowered to -\$5.08 from -\$3.48.
- Maintain Overweight rating.

Ophthotech Corp. (OPHT;OPHT US)

FYE Dec	2012A	<b>2013E</b> (Prev)	<b>2013E</b> (Curr)	2014E	2015E
EPS (\$)					
Q1 (Mar)	-	(1.05)A	(6.07)A	(0.49)	-
Q2 (Jun)	-	(1.05)A	(6.07)A	(0.51)	-
Q3 (Sep)	-	(1.84)	(10.26)A	(0.53)	-
Q4 (Dec)	-	(0.45)	(0.45)	(0.54)	-
FY	(2.52)	(3.48)	(5.08)	(2.07)	(2.26)

Source: Company data, Bloomberg, J.P. Morgan estimates. Note: Q1, Q2 2013 numbers reflect JPMe as co. still to disclose actual numbers; increaed share count plus IPO account for numbers not summing.

# Overweight

OPHT, OPHT US Price: \$26.49

Price Target: \$40.00

#### Biotechnology

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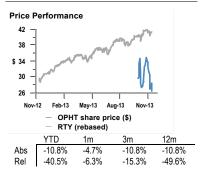
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Company Data	
Price (\$)	26.49
Date Of Price	12 Nov 13
52-week Range (\$)	36.60-23.00
Market Cap (\$ mn)	821.19
Fiscal Year End	Dec
Shares O/S (mn)	31
Price Target (\$)	40.00
Price Target End Date	31-Dec-14

#### See page 4 for analyst certification and important disclosures.

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# **Changes to Our Model**

Based on reported results and recent trends, we are making adjustments to our model. Our 2013 GAAP EPS estimate changes to -\$5.08 from -\$3.48. Our 2014-15 estimates remain unchanged at -\$2.07 and -\$2.26, respectively.

**Table 1: Changes to Our Model** 

	2013E	2013E	2014E	2014E	2015E	2015E
	OLD	NEW	OLD	NEW	OLD	NEW
R&D	27.7	27.3	47.1	47.1	58.9	58.9
SG&A	13.8	13.1	16.4	16.4	17.7	17.7
Total Op Ex	41.5	40.5	63.5	63.5	76.6	76.6
Net income	-45.8	-45.0	-66.3	-66.3	-75.6	-75.6
GAAP EPS (\$)	-3.48	-5.08	-2.07	-2.07	-2.26	-2.26
shares	14.7	10.0	32.1	32.1	33.5	33.5

Source: J.P. Morgan estimates.

### **Investment Thesis**

Fovista is the key value driver for OPHT shares. Based on the efficacy data from the phase 2b, the combination of an anti-PDGF and anti-VEGF offers potentially best-inclass efficacy with meaningful improvements against the traditional regulatory endpoints of visual acuity, as well as an underappreciated endpoint, regression of neovascularization lesions, against which traditional therapy had minimal effect. As such, we view the phase 3 results as being significantly de-risked, and believe Fovista will find use in both treatment-naïve AMD patients, and those requiring monthly anti-VEGF injections. Further, we believe Fovista has a two- to three-year headstart over other anti-PDGF therapies in development.

#### **Valuation**

Our December 2014 price target of \$40 for OPHT is based on our sum-of-the-parts NPV analysis. In order to complete our analysis, we projected sales of Fovista from a launch in 2017 through 2025. We assume a 12.5% WACC, and conservatively modeled in zero terminal values for the drug in the US and EU. Based on the projections and assumptions detailed above, as well as probability adjustments for Fovista, we derive a valuation of \$40/share, comprising US sales of Fovista of \$21/sh, OUS sales of Fovista of \$14/sh, and \$5/sh for net cash.

### **Risks to Rating and Price Target**

Key downside risks include to our price target include (1) clinical risk associated with outcome of the phase 3 studies of Fovista, (2) commercial risk that the drug will offer meaningful benefit over the current treatment paradigm as well as the impact of competing agents risk, and (3) reimbursement risk for Fovista.

# **Ophthotech: Summary of Financials**

Income Statement - Annual	FY12A	FY13E	FY14E	FY15E	Income Statement - Quarterly	1Q13A	2Q13A	3Q13A	4Q13E
Revenues	0	0	0	0	Revenues	0A	0A	0A	0
Cost of products sold	0	0	0	0	Cost of products sold	0A	0A	0A	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(7)	(13)	(16)	(18)	SG&A	(2)A	(2)A	(4)A	(4)
R&D	(7)	(27)	(47)	(59)	R&D	(3)A	(3)A	(11)A	(10)
Operating income	(14)	(40)	(64)	(77)	Operating income	(6)A	(6)A	(15)A	(14)
EBITDA	(14)	(40)	(64)	(77)	EBITDA	(6)A	(6)A	(15)A	(14)
Net interest (income) / expense					Net interest (income) / expense	-			` -
Other income / (expense)	(1)	(4)	(3)	1	Other income / (expense)	(1)A	(1)A	(1)A	(1)
Income taxes	Ó	Ó	Ô	0	Income taxes	0A	ÓA	ÔΑ	Ó
Net income - GAAP	(22)	(51)	(66)	(76)	Net income - GAAP	(9)A	(9)A	(18)A	(14)
Net income - recurring	(22)	(51)	(66)	(76)	Net income - recurring	(9)A	(9)A	(18)A	(14)
Diluted shares outstanding	` ģ	`1Ó	32	34	Diluted shares outstanding	ŽA	ŽA	ŽA	` 31
EPS - excluding non-recurring	(2.52)	(5.08)	(2.07)	(2.26)	EPS - excluding non-recurring	(6.07)A	(6.07)A	(10.26)A	(0.45)
EPS - recurring	(2.52)	(5.08)	(2.07)	(2.26)	EPS - recurring	(6.07)A	(6.07)A	(10.26)A	(0.45)
Balance Sheet and Cash Flow Data	FY12A	FY13E	FY14E	FY15E	Ratio Analysis	FY12A	FY13E	FY14E	FY15E
Cash and cash equivalents	4	170	146	177	Sales growth	-	-	_	-
Accounts receivable	0	0	0	0	EBIT growth	-	195.9%	56.9%	20.6%
Inventories	-	-	-	-	EPS growth - recurring	-	101.5%	(59.4%)	9.2%
Other current assets	0	0	0	0				, ,	
Current assets	5	171	146	177	Gross margin	-	-	-	-
PP&E	0	0	0	0	EBIT margin	-	-	-	-
Total assets	5	171	146	177	EBITDA margin	-	-	-	-
					Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	11	11	11	11	Net margin	-	-	-	-
Total liabilities	128	128	128	128	<b>S</b>				
Shareholders' equity	(123)	43	18	49	Net Debt / EBITDA	(49.2%)	393.8%	212.0%	216.3%
. ,	, ,				Net Debt / Capital (book)	(5.8%)	136.6%	115.3%	141.9%
Net income (including charges)	(15)	(51)	(66)	(76)	, ,	, ,			
D&A	Ò	Ó	0	Ó	Return on assets (ROA)	(886.3%)	(57.8%)	(41.8%)	(46.7%)
Change in working capital	0	0	0	0	Return on equity (ROE)	35.0%	125.9%	(218.9%)	(226.3%)
Other	1	0	0	0	3 ( 3 )			( /	( /
Cash flow from operations	(13)	(51)	(66)	(76)	Enterprise value / sales	_	_	_	_
	(1-7)	( /	()	()	Enterprise value / EBITDA	-	-	_	-
Capex	0	(0)	(0)	(0)	Free cash flow yield	(5.8%)	(19.2%)	(7.8%)	(8.5%)
Free cash flow	(13)	(51)	(66)	(76)	,	( /-/	,/	( /	( )
Cash flow from investing activities	0	(0)	(0)	(0)					
Cash flow from financing activities	11	217	42	107					
Dividends	-		-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

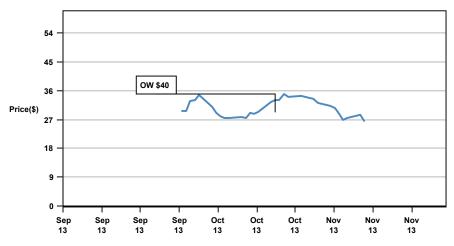
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#### Ophthotech (OPHT, OPHT US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
21-Oct-13	OW	29.25	40.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends. Initiated coverage Oct 21, 2013.

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