

Gemphire Therapeutics (GEMP - \$10.64)

Gemcabene for HoFH Shows Significant LDL Lowering

Yesterday before the open, GEMP announced positive results for gemcabene in their COBALT-1 lipid-lowering Phase 2b study. The study showed that, when added to maximally tolerated statin therapy, 600mg gemcabene could lower LDL-C an additional 28% at 8 weeks in 2 patients with homozygous familial hypercholesterolemia (HoFH). This is in-line with other approved HoFH treatments like Repatha (-31% LDL-C), Kynamro (-25% LDL-C) and Zetia (-21% LDL-C) but with a significantly cleaner Adverse Event (AE) profile. Kynamro and Juxtapid (-45% LDL-C) both have black box liver toxicity warnings and significant GI AE's. So while the sample size (n=2) is admittedly low, we see this as a good precursor to how the full data set should read out in June 2017. Additionally we believe that the strong LDL-C lowering effect seen in COBALT (see Figure 1 on next page) could be a good proxy for how the ROYAL-1 trial in atherosclerotic cardiovascular disease (ASCVD) might look, given that the HoFH patients are some of the "worst-case" patients. Following this encouraging HoFH data and with multiple additional catalysts throughout 2017, we still believe GEMP is undervalued at these levels and we are reiterating our Buy rating and our \$20 price target.

- **Clean AE profile a real, significant benefit in gemcabene.** The -28% LDL-C lowering effect seen at week 8 is a meaningful change, and in-line with other HoFH treatments, but what we find most compelling is the clean AE profile. Other products have multiple AE's and even black box liver toxicity warnings, which should help gemcabene distinguish itself in a competitive market.
- **NASH pre-clinical trial also a positive, and another huge market.** While GEMP is already targeting the impressive CVD market (~14M in US), they are now one step closer to starting a Phase 2 clinical trial in another large indication, NASH (~7-8M in US).
- **Multiple key catalysts still to come.** The full top-line COBALT trial data is expected June 2017, the ROYAL data in ASCVD is still expected to read out in 3Q17, and the INDIGO data in severe hypertriglyceridemia in 4Q17 (see Figure 3 on the next page for the clinical trials timeline).
- **Reiterate Buy, \$20 PT.** Our PT is based on a sum-of-the-parts with gemcabene worth \$18/share and cash (end '17) and tech value \$2/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	(0.88)	(1.00)	(0.81)	(0.84)	(3.50)	NA
FY-17E	(0.55)	(0.45)	(0.45)	(0.42)	(1.85)	NA
FY-16E	(0.61)A	(0.38)A	(0.47)A	(0.59)	(2.10)	NA
FY-15	NA	NA	NA	NA	(3.14)	NA

Source: Company data and Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	GEMP
Rating:	Buy
Price Target:	\$20.00

Trading Data:

Last Price (01/30/2017)	\$10.64
52-Week High (08/31/2016)	\$13.98
52-Week Low (12/13/2016)	\$7.25
Market Cap. (MM)	\$98.3
Shares Out. (MM)	9.27

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Figure 1: COBAL-1 Interim Data

Patient	Gender	HoFH Entry Criteria	Maximal Lipid-Lowering Therapies	Baseline LDL-C mg/dL	% Change From Baseline, Gemcabene 300 mg/day (4 weeks)	% Change From Baseline, Gemcabene 600 mg/day (4 weeks)
1	Male	Genotype (Compound Heterozygous)	Rosuvastatin 40mg	138	-28.7%	-32.4%
2	Male	Genotype (Compound Heterozygous)	Atorvastatin 80mg Ezetimibe 10mg	195	-18.3%	-22.9%

Source: Laidlaw & Company estimates.

Figure 2: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Gemcabene	\$263,426	\$18.00
Cash (end of '16E)	\$1,825	\$2.00
	\$265,251	\$20.00
2017 fully diluted shares out (000)		14,421

Source: Gemphire presentation

Figure 3: Clinical trials timeline

	2015A		2016E				2017E				2018E				2019E				2020E				2021E			
	1QA	2QA	3QA	4QA	1QA	2QA	3QA	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE	1QE	2QE	3QE	4QE		
Gemphire Therapeutics Inc.																										
Potential clinical trial timeline estimates																										
Homozygous Familial Hypercholesterolemia (HoFH) - Orphan Drug Designation																										
COBAL-1																										
Phase 2b - HoFH; Interim data wk of Jan 30, '17; full data July '17																										
Phase 3																										
NDA filing, FDA approval, launch																										
Partner for all three indications																										
EU filing, approval & launch																										
Hypercholesterolemia - HeFH & ASCVD																										
ROYAL-1																										
Phase 2b - 1st patient 11/28/16; fully enrolled Jan. '17																										
Phase 3																										
Partner for all three indications																										
NDA filing, FDA approval, launch																										
Severe Hypertriglyceridemia (SHTG)																										
INDIGO-1																										
Phase 2b - 1st patients enrolled December '16																										
Phase 3																										
Partner for all three indications																										
NDA filing, FDA approval, launch																										

Source: Company reports; Laidlaw & Company estimates.

Figure 4: Quarterly Income Statement

Gemphire											
Quarterly income statement											
	2015A	2016E				2016E	2017E				2017E
	Year	1QA	2QA	3QA	4QE	Year	1QE	2QE	3QE	4QE	Year
(\$000's except per share)											
SG&A	3,177	1,050	1,051	1,066	1,150	4,317	1,500	1,500	1,750	1,750	6,500
R&D	3,991	1,176	789	1,769	4,200	7,934	3,800	4,000	4,000	4,000	15,800
Acqrd IPR&D	908					0					0
Operating income/(loss)	(8,076)	(2,226)	(1,840)	(2,835)	(5,350)	(12,251)	(5,300)	(5,500)	(5,750)	(5,750)	(22,300)
Interest (exp) income	(762)	127	449	(476)	50	150	50	50	50	50	200
Conv note extinguish	(198)					0					0
Other	7	(4)				(4)					0
Total other loss	(953)	123	449	(476)	50	146	50	50	50	50	200
Adj-Net income/(loss)	(9,029)	(2,103)	(1,391)	(3,311)	(5,300)	(12,105)	(5,250)	(5,450)	(5,700)	(5,700)	(22,100)
Share based comp				567	800	1,367					
Series A convert premium	(2,968)	(149)	(150)	(67)	(150)	(516)					
Other convert premium	(1,047)					0					
NI/(loss) as reported	(13,044)	(2,252)	(1,541)	(3,945)	(6,250)	(13,988)					
Adj-EPS ex-non-cash	(\$3.14)	(\$0.61)	(\$0.38)	(\$0.47)	(\$0.59)	(\$2.10)	(\$0.55)	(\$0.45)	(\$0.45)	(\$0.42)	(\$1.85)
EPS as reported	(\$4.54)	(\$0.65)	(\$0.42)	(\$0.56)	(\$0.70)	(\$2.43)					
Shares out (000)	2,875	3,469	3,627	6,984	8,984	5,766	9,484	11,984	12,734	13,484	11,921
Fully diluted shares (000)	5,100	5,567	6,394	9,123	11,484	8,142	11,984	14,484	15,234	15,984	14,421

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

Figure 5: Annual Income Statement

Gemphire								
Annual income statement								
(\$000's except per share)	2015A	2016E	2017E	2018E	2019E	2020E	2021E	Comments
Revenues								
Gemcabene royalty					\$19	\$124	\$40,775	HoFH launch 4Q19, other indications 2021 Royalties from partner
Total sales					\$19	\$124	\$40,775	
COGS	0	0	0	0	0	0	0	partner manufactures drug
Gross margin	0	0	0	0	19	124	40,775	
SG&A	3,177	4,317	6,500	9,750	19,000	18,000	23,250	
R&D	3,991	7,934	15,800	50,850	43,500	49,800	50,250	
Operating income/(loss)	(8,076)	(12,251)	(22,300)	(60,600)	(62,481)	(67,676)	(32,726)	
Interest expense	(762)	150	200	300	300	400	400	
Conv note extinguish	(198)	0	0	0	0	0	0	
Other	7	(4)	0	0	0	0	0	
Total other loss	(953)	146	200	300	300	400	400	
Adj-Net income/(loss)	(9,029)	(12,105)	(22,100)	(60,300)	(62,181)	(67,276)	(32,326)	
Series A convert premium	(2,968)	(516)	0	0	0	0	0	
Other convert premium	(1,047)	0	0	0	0	0	0	
NI/(loss) as reported	(13,044)	(13,988)	0	0	0	0	0	
Adj-EPS ex-non-cash	(\$3.14)	(\$2.10)	(\$1.85)	(\$3.50)	(\$2.65)	(\$2.55)	(\$1.05)	
EPS as reported	(\$4.54)	(\$2.43)						
Shares out (000)	2,875	5,766	11,921	17,234	23,484	26,359	30,734	
Fully diluted shares (000)	5,100	8,142	14,421	19,984	26,484	29,359	33,984	
Cash balance	\$3,620	(\$5,675)	\$11,950	\$61,345	\$90,304	\$23,593	(\$7,983)	

Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

Major risks

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.

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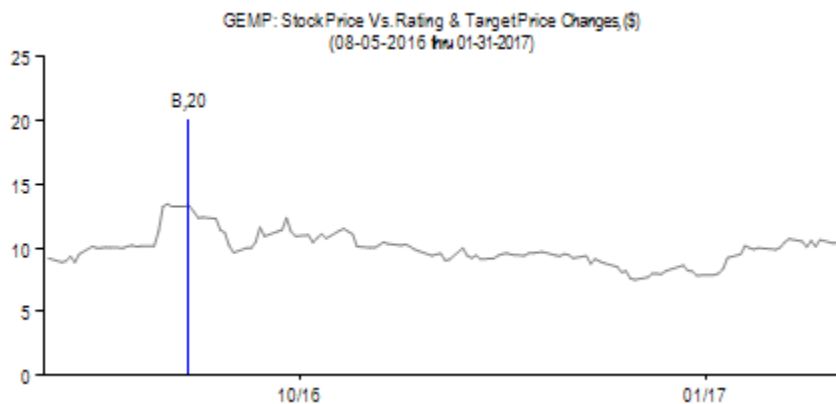
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
09/06/2016	Buy (B)	13.28

3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
09/06/2016	20.00	13.28

Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	60.98%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.44%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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