

Gemphire Therapeutics (GEMP – \$9.61)

While Not in the Most Convincing Way, ROYAL-1 Hits Endpoint

GEMP recently announced top-line data from their Phase 2b ROYAL-1 trial evaluating safety/efficacy of 600mg gemcabene for 12 weeks in patients (n=105) not adequately controlled (LDL-C \geq 100mg/dl and TG < 500mg/dL) on stable high or moderate-intensity statin and/or ezetimibe therapy. Although gemcabene hit its primary endpoint demonstrating a mean percent reduction in LDL-C of 17.2% vs. 5.5% in placebo (p=0.0057), we were expecting greater reduction as prior Phase 2 trial (1027-018) showed a 25% and 31% lowering in LDL-C for gemcabene 300mg and 900mg groups, respectively. We were encouraged by gemcabene's ability to lower hsCRP by 40% vs. 6.1% for placebo and look forward to getting more secondary results in the near term such as the variation in LDL-C reduction in moderate vs. high intensity statin (6%-8% on high intensity in real-world setting). While efficacy data wasn't as convincing as we had anticipated, we were encouraged by safety as there were no serious AEs and no signs of drug-drug interactions perceived. This positive safety read-out is especially encouraging since many may have doubted the significance of safety in COBALT-1 (n=8). After speaking with management, we look forward to hearing more details about the data as well as GEMP's future development plans. In terms of catalysts, GEMP still anticipates starting their Phase 2 AZURE-1 trial in NASH in 2H17 and expect data read-out of their Phase 2b INDIGO-1 study in SHTG patients in 1Q18. While we do believe the relative weakness of this top-line efficacy read-out adds risk to the story, we view the sell-off as overdone and see an interesting opportunity at these levels. We are lowering our price target from \$25 to \$20 and reiterating our Buy rating.

- **Efficacy lower than anticipated, still hit primary endpoint.** Although gemcabene wasn't able to lower LDL-C as much as anticipated, we would like to remind investors that the study hit its primary endpoint with p=0.0057 in more difficult circumstances than their previous 1027-18 study.
- **Safety and inflammation signal, not to be underestimated.** No serious AEs or drug interactions and only one discontinuation in gemcabene arm vs. two in the placebo group is a real positive, in our opinion, as other products have multiple AE's and even black box liver toxicity warnings.
- **Reiterate Buy, lowering PT to \$20.** Our PT is based on a sum-of-the-parts with Gemcabene worth \$19/share and cash (end'17) and tech value \$1/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	(1.05)	(1.18)	(0.98)	(1.05)	(4.23)	NA
FY-17E	(0.69)A	(0.80)	(0.63)	(0.59)	(2.70)	NA
FY-16	(0.61)	(0.38)	(0.47)	(0.68)	(2.22)	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

Trading Data:

Last Price (08/07/2017)	\$961
52-Week High (08/01/2017)	\$21.59
52-Week Low (12/13/2016)	\$7.25
Market Cap. (MM)	\$102.1
Shares Out. (MM)	10.6

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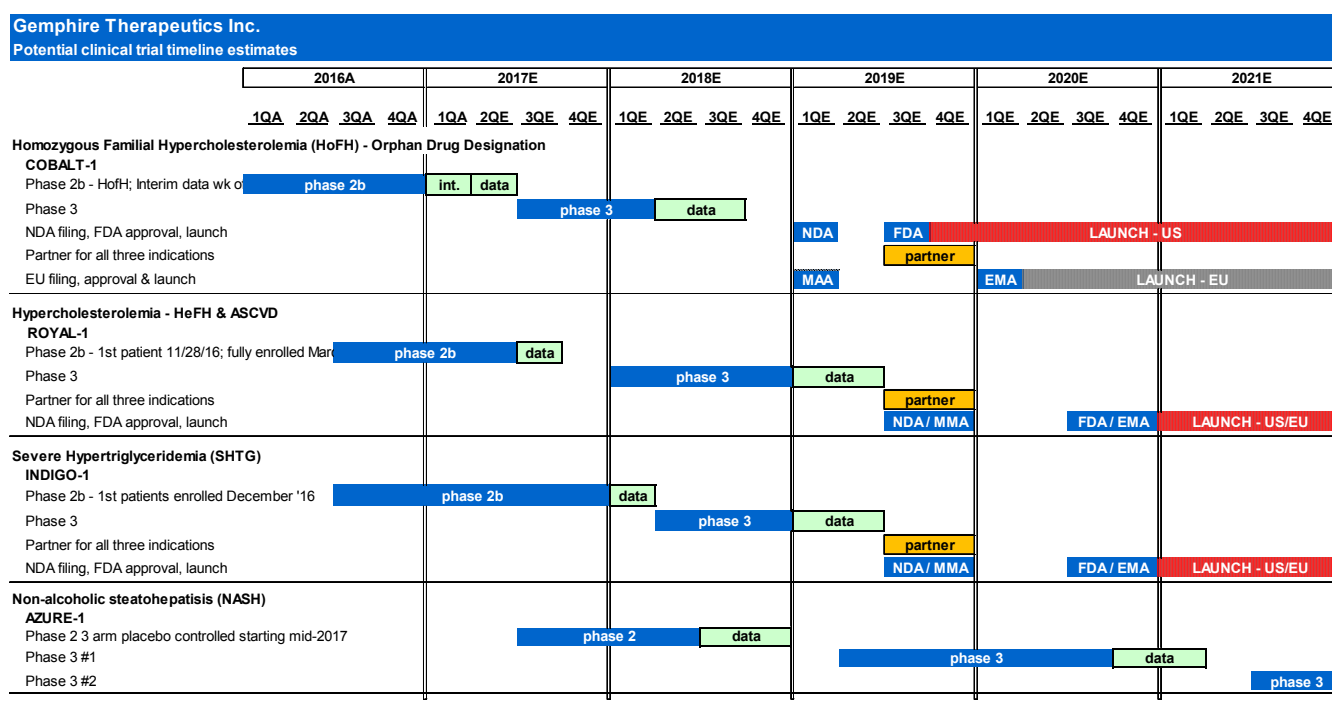
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Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Gemcabene	\$263,426	\$19.00
Cash (end of '17E)	\$14,449	\$1.00
	\$277,875	\$20.00
2017 fully diluted shares out (000)		13,659

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: Quarterly Income Statement

Gemphire										
Quarterly income statement										
(\$000's except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QE	3QE	4QE	
SG&A	1,050	1,051	1,066	1,489	4,790	1,623	2,000	1,750	1,750	7,123
R&D	1,176	789	1,769	4,839	8,188	4,980	6,100	5,000	5,000	21,080
Acqrd IPR&D					0					0
Operating income/(loss)	(2,226)	(1,840)	(2,835)	(6,328)	(12,978)	(6,603)	(8,100)	(6,750)	(6,750)	(28,203)
Interest (exp) income	127	449	(476)	14	114	7	50	50	50	157
Interest (exp) SVB								(77)	(116)	(193)
Conv note extinguish					0					0
Other	(4)				(4)					0
Total other loss	123	449	(476)	14	110	7	50	(27)	(66)	(36)
Adj-Net income/(loss)	(2,103)	(1,391)	(3,311)	(6,314)	(12,868)	(6,596)	(8,050)	(6,777)	(6,816)	(28,239)
Share based comp			567	900	1,718	900				
Series A convert premium	(149)	(150)	(67)		(366)					
Other convert premium										
NI/(loss) as reported	(2,252)	(1,541)	(3,945)	(7,214)	(14,952)	(7,496)				
Adj-EPS ex-non-cash	(\$0.61)	(\$0.38)	(\$0.47)	(\$0.68)	(\$2.22)	(\$0.69)	(\$0.80)	(\$0.63)	(\$0.59)	(\$2.70)
EPS as reported	(\$0.65)	(\$0.42)	(\$0.56)	(\$0.78)	(\$2.57)	(\$0.79)				
Shares out (000)	3,469	3,627	6,984	9,264	5,809	9,521	10,021	10,771	11,521	10,459
Fully diluted shares (000)	5,567	6,394	9,123	11,514	8,150	12,721	13,221	13,971	14,721	13,659

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

Figure 4: Annual Income Statement

Gemphire							
Annual income statement							
(\$000's except per share)	2016A	2017E	2018E	2019E	2020E	2021E	Comments
Revenues							
Gemcabene royalty				\$19	\$124	\$40,775	HoFH launch 4Q19, royalties other indications 2021
Total sales				\$19	\$124	\$40,775	Royalties from partner
SG&A	4,790	7,123	8,000	12,000	18,000	22,250	
R&D	8,188	21,080	52,500	55,250	53,500	53,500	
Operating income/(loss)	(12,978)	(28,203)	(60,500)	(67,231)	(71,376)	(34,976)	
Interest expense	114	157	300	300	400	400	
Total other loss	110	(36)	(73)	53	153	379	
Adj-Net income/(loss)	(12,868)	(28,239)	(60,573)	(67,178)	(71,223)	(34,596)	
Series A convert premium	(366)	0	0	0	0	0	
NI/(loss) as reported	(14,952)	0	0	0	0	0	
Adj-EPS ex-non-cash	(\$2.22)	(\$2.70)	(\$4.23)	(\$3.30)	(\$3.17)	(\$1.29)	
EPS as reported	(\$2.57)						
Shares out (000)	5,809	10,459	14,316	20,362	22,487	26,862	
Fully diluted shares (000)	8,150	13,659	17,516	23,762	25,987	30,362	

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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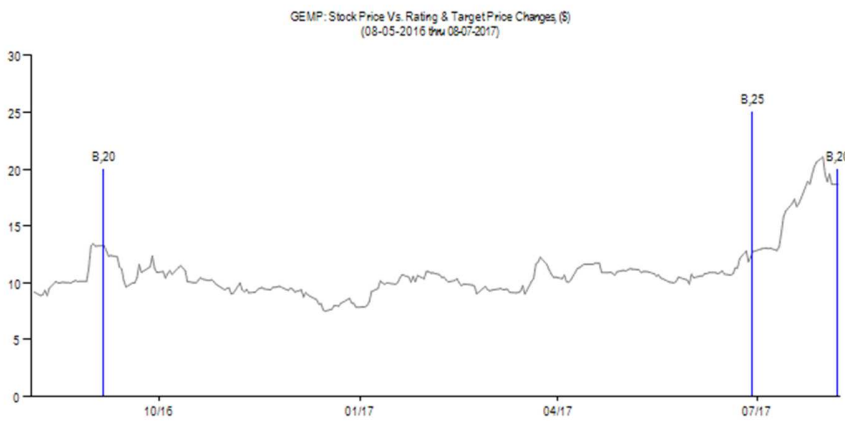
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Additional information available upon request.

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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
09/06/2...	Buy (B)	13.28

3 Year Price Change History

Date	Target Price (\$)	Closing Price (\$)
09/06/2...	20.00	13.28
06/29/2...	25.00	12.76
08/07/2...	20.00	18.66*

* Previous Close 8/4/2017

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	63.04%	30.43%	2.17%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.35%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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