

## Gemphire Therapeutics (GEMP – \$9.58)

### As a Whole, Gemcabene’s Profile Appears to be Phase 3 Ready

Last night after the close, GEMP held a conference call announcing its plans to advance gemcabene into Phase 3 clinical trials as well as discussing their new analysis to date on their hypercholesterolemic patients including recently completed COBALT-1 and ROYAL-1 trials. This extensive analysis demonstrated gemcabene’s ability to reduce LDL-C by 21% in hypercholesterolemic patients and by 25% in mixed dyslipidemia. Combined with impressive safety across 956 subjects and 20 Phase 1 and Phase 2 clinical trials, this represents a real positive, in our opinion. Although we were hoping to get more details concerning the ROYAL-1 data that sent GEMP shares down ~50%, we will have to remain patient until this full data set is presented at the American Heart Association’s (AHA) Scientific Sessions this upcoming November. GEMP also announced that COBALT-1 full results will be presented at the FH Foundation’s Summit meeting on 9/25/17. As a reminder, while ROYAL-1’s 17.2% LDL-C reduction came in below our anticipated ~25% reduction, we were particularly impressed with its ability to lower hsCRP by 40% vs 6.1% for placebo. This reduction in inflammation is especially important as Novartis’ CANTOS trial recently demonstrated reduction of inflammation and hsCRP as a potential novel mechanism to decrease cardiovascular disease (CVD). With this robust profile, GEMP intends to meet with the FDA in early 2018 to discuss Phase 3 trial designs. While few details were given, GEMP’s Phase 2b INDIGO-1 trial might take a little longer to read-out as recent hurricanes could have delayed certain centers. Finally, GEMP intends to initiate its proof-of-concept in NASH in 4Q17. We reiterate our Buy rating and \$20 price target.

- **ROYAL-1 details will have to wait until November.** Although we were hoping to get a more granular breakdown of the ROYAL-1 in terms of number of patients on high vs moderate statins and TG levels, we are encouraged that GEMP remains confident in their goal to proceed with Phase 3 clinical trials.
- **New analysis of total data, gemcabene’s profile remains impressive.** With a total of 956 subjects and 20 successful Phase 1 and 2 clinical trials, we continue to see gemcabene’s safety/efficacy, cost efficiency and convenience as key differentiators.
- **Reiterate Buy, \$20 PT.** Our PT is based on a sum-of-the-parts with gemcabene worth \$18/share and cash (end’18) and tech value \$2/share.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-18E</b>	(0.99)	(1.13)	(0.94)	(1.02)	(4.07)	NA
<b>FY-17E</b>	(0.69)A	(0.75)A	(0.60)	(0.56)	(2.58)	NA
<b>FY-16</b>	(0.61)	(0.38)	(0.47)	(0.68)	(2.22)	NA
<b>FY-15</b>	NA	NA	NA	NA	(3.14)	NA

#### Healthcare/Biotechnology

Ticker:	<b>GEMP</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$20</b>

#### Trading Data:

Last Price (09/19/2017)	\$9.58
52-Week High (08/01/2017)	\$21.58
52-Week Low (08/10/2017)	\$7.20
Market Cap. (MM)	\$102.6
Shares Out. (MM)	10.6

#### Analyst

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Source: Company data and Laidlaw & Company estimates

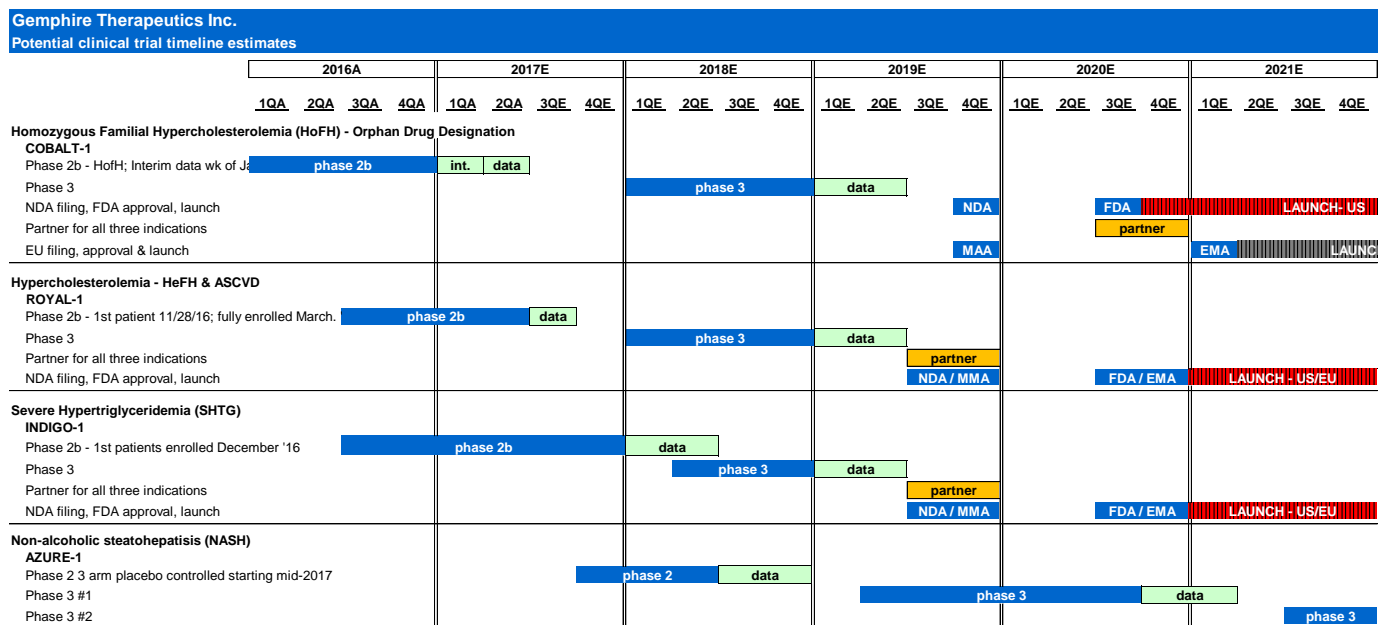
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Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Gemcabene	\$328,007	\$18.00
Cash (end of '18E)	\$43,019	\$2.00
	\$371,026	<b>\$20.00</b>
2018 fully diluted shares out (000)		18,098

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: Quarterly Income Statement

<b>Gemphire</b>										
<b>Quarterly income statement</b>										
(\$000's except per share)	2016A				2016A Year	2017E				2017E Year
	1QA	2QA	3QA	4QA		1QA	2QA	3QE	4QE	
SG&A	1,050	1,051	1,066	1,489	4,790	1,623	2,078	1,750	1,750	7,201
R&D	1,176	789	1,769	4,839	8,188	4,980	5,837	5,000	5,000	20,817
Acqrd IPR&D					0					0
<b>Operating income/(loss)</b>	<b>(2,226)</b>	<b>(1,840)</b>	<b>(2,835)</b>	<b>(6,328)</b>	<b>(12,978)</b>	<b>(6,603)</b>	<b>(7,915)</b>	<b>(6,750)</b>	<b>(6,750)</b>	<b>(28,018)</b>
Interest (exp) income	127	449	(476)	14	114	7	13	50	50	120
Interest (exp) SVB								(77)	(116)	(193)
Conv note extinguish					0					0
Other	(4)				(4)					0
<b>Total other loss</b>	<b>123</b>	<b>449</b>	<b>(476)</b>	<b>14</b>	<b>110</b>	<b>7</b>	<b>13</b>	<b>(27)</b>	<b>(66)</b>	<b>(73)</b>
<b>Adj-Net income/(loss)</b>	<b>(2,103)</b>	<b>(1,391)</b>	<b>(3,311)</b>	<b>(6,314)</b>	<b>(12,868)</b>	<b>(6,596)</b>	<b>(7,902)</b>	<b>(6,777)</b>	<b>(6,816)</b>	<b>(28,091)</b>
Share based comp			567	900	1,718	900	2,600			
Series A convert premium	(149)	(150)	(67)		(366)					
Other convert premium										
<b>NI/(loss) as reported</b>	<b>(2,252)</b>	<b>(1,541)</b>	<b>(3,945)</b>	<b>(7,214)</b>	<b>(14,952)</b>	<b>(7,496)</b>	<b>(10,502)</b>			
<b>Adj-EPS ex-non-cash</b>	<b>(\$0.61)</b>	<b>(\$0.38)</b>	<b>(\$0.47)</b>	<b>(\$0.68)</b>	<b>(\$2.22)</b>	<b>(\$0.69)</b>	<b>(\$0.75)</b>	<b>(\$0.60)</b>	<b>(\$0.56)</b>	<b>(\$2.58)</b>
<b>EPS as reported</b>	<b>(\$0.65)</b>	<b>(\$0.42)</b>	<b>(\$0.56)</b>	<b>(\$0.78)</b>	<b>(\$2.57)</b>	<b>(\$0.79)</b>	<b>(\$0.99)</b>			
Shares out (000)	3,469	3,627	6,984	9,264	5,809	9,521	10,603	11,353	12,103	10,895
Fully diluted shares (000)	5,567	6,394	9,123	11,514	8,150	12,721	13,803	14,553	15,303	14,095

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

Figure 4: Annual Income Statement

<b>Gemphire</b>							
<b>Annual income statement</b>							
(\$000's except per share)	<b>2016A</b>	<b>2017E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>	<b>2021E</b>	<b>Comments</b>
<b>Revenues</b>							
Gemcabene royalty				\$0	\$19	\$33,874	HoFH launch 4Q20, royalties other indications 2021
<b>Total sales</b>				<b>\$0</b>	<b>\$19</b>	<b>\$33,874</b>	<b>Royalties from partner</b>
SG&A	4,790	7,201	8,000	12,000	18,000	22,250	
R&D	8,188	20,817	52,500	55,250	53,500	53,500	
<b>Operating income/(loss)</b>	<b>(12,978)</b>	<b>(28,018)</b>	<b>(60,500)</b>	<b>(67,250)</b>	<b>(71,481)</b>	<b>(41,876)</b>	
Interest expense	114	120	300	300	400	400	
<b>Total other loss</b>	<b>110</b>	<b>(73)</b>	<b>(73)</b>	<b>53</b>	<b>153</b>	<b>379</b>	
<b>Adj-Net income/(loss)</b>	<b>(12,868)</b>	<b>(28,091)</b>	<b>(60,573)</b>	<b>(67,197)</b>	<b>(71,328)</b>	<b>(41,497)</b>	
Series A convert premium	(366)	0	0	0	0	0	
<b>NI/(loss) as reported</b>	<b>(14,952)</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
<b>Adj-EPS ex-non-cash</b>	<b>(\$2.22)</b>	<b>(\$2.58)</b>	<b>(\$4.07)</b>	<b>(\$3.21)</b>	<b>(\$3.09)</b>	<b>(\$1.51)</b>	
<b>EPS as reported</b>	<b>(\$2.57)</b>						
Shares out (000)	5,809	10,895	14,898	20,944	23,069	27,444	
Fully diluted shares (000)	8,150	14,095	18,098	24,344	26,569	30,944	

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

## Major risks

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**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.

## DISCLOSURES:

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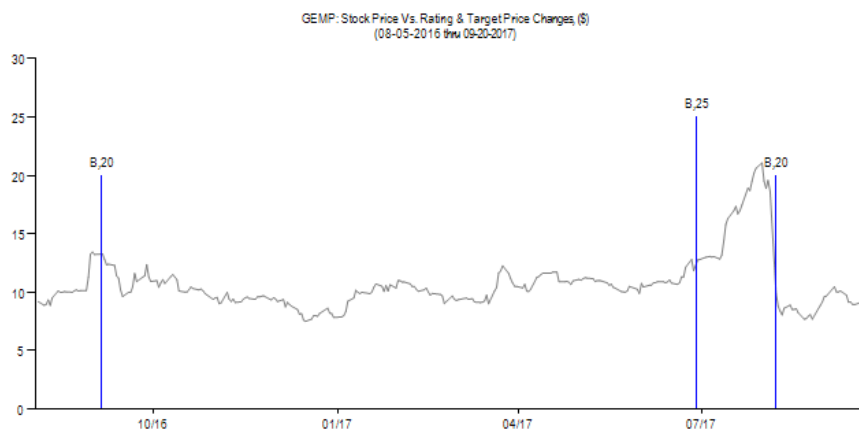
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### Rating and Price Target Change History



#### 3 Year Rating Change History

Date	Rating	Closing Price (\$)
09/06/2...	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	12.16
08/07/2...	20.00	9.93

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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	64.58%	31.25%	2.08%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.17%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Novartis AG (NVS – Not Rated)

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