October 30, 2017

## **Gemphire Therapeutics (GEMP – \$10.22)**

Lessons Learned, GEMP Eager to Move into Phase 3

We recently spent time with GEMP's senior management and come away incrementally more positive as downside seems more than priced in at these levels. After GEMP was slashed by ~50% following their Phase 2b ROYAL-1 data (17.2% LDL-C reduction vs. 5.5% for placebo, which actually hit statistical significance), we continue to believe the stock reaction resulted from Street expectations of greater LDL-C reduction (~25%) rather than weakness in GEMP's fundamentals. While GEMP could have more adequately communicated that ROYAL-1 was primarily powered for safety, we view their integrated analysis demonstrating 21% LDL-C reduction in hypercholesterolemic patients and by 25% in mixed dyslipidemia with impressive safety across 956 subjects and 20 Phase 1 and 2 clinical trials as Phase 3 ready. While ~50% of patients in ROYAL-1 were on high intensity statins, we expect their Phase 3 trial to be more reflective of reality (~7% on high intensity). For more details related to percentage of patients on different intensities of statin, we look forward to seeing their full data set presented at the American Heart Association's (AGA) meeting in a few weeks. We were also encouraged by GEMP's intention to use a placebo run-in design in Phase 3 in order to appropriately eliminate placebo responders. As ROYAL-1 demonstrated hsCRP reduction of 40%, we continue to see Novartis' recent CANTOS trial demonstrating a potential correlation between inflammation and cardiovascular related MACE as a real positive. Although  $\sim 1/3$  of clinical trial centers were affected by the recent hurricanes, we still expect Phase 2b INDIGO-1 to read out in 1H18. While poor messaging might have led GEMP to a significant valuation reduction, we see gemcabene's fundamentals as solid and reiterate our Buy rating and \$20 price target.

- **Miscommunication in the past, new opportunity might have opened at GEMP.** While GEMP could have better communicated to investors that ROYAl-1 was mostly designed for safety rather than efficacy, we believe GEMP will be approaching their end of Phase 2 meeting with FDA in 1Q18 with strong data.
- Integrated analysis shows strong efficacy and very impressive safety. Across 20 successful Phase 1 and 2 clinical trials in 956 patients, we are especially impressed with gemcabene's safety profile as we continue to view as either an addon or a backbone therapy with significant cost efficiency.
- **Reiterate Buy, \$20 PT.** Our PT is based on a sum-of-the-parts with gemcabene worth \$18.5/share and cash (end'18) and tech value \$1.5/share.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E	
FY-18E	(0.99)	(1.12)	(0.98)	(1.05)	(4.13)	NA	
<b>FY-17E</b>	(0.69)A	(0.75)A	(0.59)	(0.56)	(2.57)	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:	<b>GEMP</b>
Rating:	Buy
Price Target:	\$20

#### **Trading Data:**

Last Price (10/27/2017)	\$10.22
52-Week High (08/01/2017)	\$21.59
52-Week Low (08/10/2017)	\$7.20
Market Cap. (MM)	\$108.7
Shares Out. (MM)	10.6

#### **Analyst**

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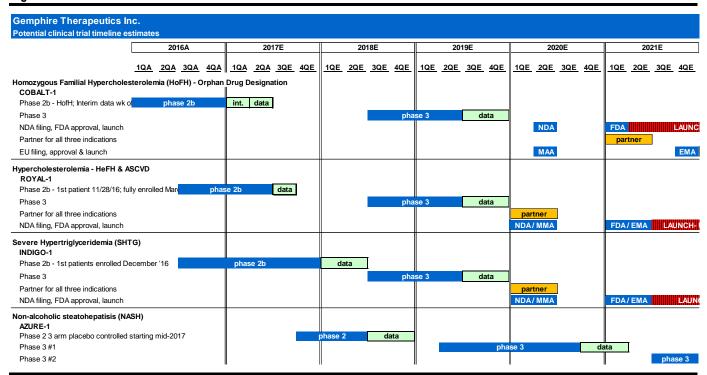
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Figure 1: Valuation

Sum-of-the-parts valuation		
Segment	Valuation (000's)	Per share value
Gemcabene	\$328,007	\$18.50
Cash (end of '18E)	\$24,613	\$1.50
	\$352,621	\$20.00
2018 fully diluted shares out (000	0)	17,803

Source: Laidlaw & Company estimates.

Figure 2: Clinical trials timeline



Source: Company reports; Laidlaw & Company estimates.

Figure 3: Quarterly Income Statement

Gemphire										
Quarterly income staten	nent									
	2016A			2016A	2017E				2017E	
(\$000's except per share)	1QA	2QA	3QA	4QA	<u>Year</u>	1QA	2QA	3QE	4QE	<u>Year</u>
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					C
Operating income/(loss)	(2,226)	(1,840)	(2,835)	(6,328)	(12,978)	(6,603)	(7,915)	(6,750)	(6,750)	(28,018
Interest (exp) income	127	449	(476)	14	114	7	13	50	50	_ 120
Interest (exp) SVB								(20)	(30)	(51
Conv note extinguish					0					C
Other Total other loss	( <u>4)</u> 1 <b>23</b>	449	(476)	14	110	7	13	30	20	<b>6</b> 9
			(476)							
Adj-Net income/(loss)	(2,103)	(1,391)	(3,311)	(6,314)	(12,868)	(6,596)	(7,902)	(6,720)	(6,730)	(27,949
Share based comp			567	900	1,718	900	2,600			
Series A convert premium	(149)	(150)	(67)	000	(366)		2,000			
Other convert premium	. ,	. ,	. ,		, ,					
NI/(loss) as reported	(2,252)	(1,541)	(3,945)	(7,214)	(14,952)	(7,496)	(10,502)			
Adj-EPS ex-non-cash EPS as reported	(\$0.61) (\$0.65)	(\$0.38) (\$0.42)	(\$0.47) (\$0.56)	(\$0.68) (\$0.78)	(\$2.22) (\$2.57)	(\$0.69) (\$0.79)	(\$0.75) (\$0.99)	(\$0.59)	(\$0.56)	(\$2.57
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 & 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				\$0	\$0	\$16,946	HoFH launch, royalties other indications 2021
Total sales				\$0	\$0	\$16,946	Royalties from partner
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	
Operating income/(loss)	(12,978)	(28,018)	(60,500)	(67,250)	(71,500)	(58,804)	
Interest expense	114	120	300	300	400	400	
Total other loss	110	69	179	179	279	390	
Adj-Net income/(loss)	(12,868)	(27,949)	(60,321)	(67,071)	(71,221)	(58,414)	
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 EPS as reported	(\$2.22) (\$2.57)	(\$2.57)	(\$4.13)	(\$3.42)	(\$3.10)	(\$2.18)	
Shares out (000)	5,809	10,895	14,603	19,603	22,999	26,835	
Fully diluted shares (000)	8,150	14,095	17,803	23,003	26,499	30,335	

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.

October 30, 2017 Es

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#### Additional information available upon request.

Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months

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# 3 Year Rating Change History Date Rating Closing Price (\$) 09/06/2... Buy (B) 13.28

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Source: Laidlaw & Company

Created by: Blue-Compass.net

Laidlaw & C	ompany Rating System*	% of Companies Under Coverage	% of Companies for which Laidlaw & Company has performed services for in the last 12 months		
		With This Rating	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.	62.50%	31.25%	2.08%	
Hold (H)	Expected returns to be in line with the sector average over 12 months.	6.25%	0.00%	0.00%	
Sell (S)	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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