

Flexion Therapeutics (FLXN - \$24.42)

Healthcare / Biotechnology

Product-Specific Q Code for Zilretta, a Pleasant Surprise

FLXN recently announced that Centers for Medicare Services (CMS) issued a product specific Q code for Zilretta (Q9993), which will be effective as of 7/1/18. We view this update as a pleasant surprise since CMS issues such a code when they see a programmatic need to differentiate a drug from competition. This code will cover Medicare claims for Zilretta injected in a physician's office (~50% of US market) and should enable quicker adjudication of Medicare claims than under a miscellaneous code. Q9993 should help speed up claims processing from 30-60 days to 2-3 weeks. This code comes on the heels of their issued product-specific C code (C9469) for Medicare claims for hospital outpatients (effective 4/1/18). After speaking with management, it seems to only improve Zilretta's odds of ultimately getting their product specific J-Code, which was filed in late 2017 and could be effective as of 1/1/19. FLXN's main focus remains on their launch. However, they recently announced the discontinuation of their FX-101 (2x Zilretta's extended release profile in pre-clinical trials). We believe this action could increase their M&A appetite as they maintain their interest in having three quality shots on goal. We continue to expect their PK/safety of bilateral knee OA to readout in 2Q18, repeat dose in 3Q18 (potentially label expanding), and shoulder and hip data in 2H18. With increased confidence in FLXN ultimately getting their product specific J-Code, we view this Q code as a pleasant surprise and reiterate out Buy Rating and \$38 price target.

- **New Q code, a pleasant surprise with potentially encouraging long-term implications.** As FLXN didn't apply for this product specific Q-code, we view it as a net positive that could potentially increase their odds of obtaining their important J-Code, which would be effective as of 1/1/19.
- **2018 set to be exciting catalyst-filled year with potential M&A.** We continue to expect PK/safety data in bilateral knee OA in 2Q18, repeat dose in 3Q18 as well as shoulder and hip readout in 2H18. Additionally, with FX101 discontinued, we believe FLXN could be looking to grow their pipeline.
- **Maintain BUY rating and \$38 price target.** Our \$38 price target is based on a sum-of-the-parts analysis, with Zilretta valued at \$33/share and cash (end '18) and technology at \$5/share.

Ticker:	FLXN
Rating:	Buy
Price Target:	\$38

Trading Data:

Last Price (04/03/2018)	\$24.42
52-Week High (10/06/2017)	\$32.25
52-Week Low (06/15/2017)	\$16.51
Market Cap. (MM)	\$918.7
Shares Out. (MM)	37.6

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY18E	(\$1.25)	(\$1.21)	(\$1.06)	(\$1.01)	(\$4.76)	NA
FY17A	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	NA
FY16A	(\$0.64)	(\$0.63)	(\$0.65)	(\$0.89)	(\$2.84)	NA
FY15A	(\$0.43)	(\$0.58)	(\$0.52)	(\$0.63)	(\$2.15)	NA

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Source: Company data and Laidlaw & Company estimates

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Figure 1: Valuation

Sum-of-the-parts value		
Segment	Valuation (000's)	Per share value
FX006 value	\$1,310,114	\$33
Cash (end '18) & tech value	\$180,097	\$5
SUM	\$1,490,211	\$38
Shares out '18E (000)		39,977

Source: Company Reports: Laidlaw & Company estimates

Figure 3: Quarterly Income Statement

Flexion Therapeutics										
Quarterly income statement										
(\$000 except per share)	2017A				2017A Year	2018E				2018E Year
	1QA	2QA	3QA	4QA		1QE	2QE	3QE	4QE	
Revenues										
Total Revenue				\$355	\$355	\$4,092	\$5,456	\$6,820	\$8,866	\$25,233
Expenses:										
Cost of Revenue (COGS)	-	-	-	4	4	409	546	682	887	2,523
Gross Margin	-	-	-	351	351	3,683	4,910	6,138	7,979	22,709
R&D	10,756	11,769	12,846	15,860	51,231	17,500	17,500	17,500	17,500	70,000
SG&A	13,026	15,133	18,375	32,267	78,801	30,150	30,150	30,150	30,150	120,600
Total op. exp.	23,782	26,902	31,221	48,127	130,032	47,650	47,650	47,650	47,650	190,600
Inc (loss) from Ops	(23,782)	(26,902)	(31,221)	(47,776)	(129,681)	(43,967)	(42,740)	(41,512)	(39,671)	(167,891)
Int inc (exp), net	(75)	(2,090)	(2,748)	(2,637)	(7,550)	(2,750)	(2,750)	(2,750)	(2,750)	(10,000)
Other income (exp)	(22)	112	(219)	(121)	(250)	(100)	(100)	(100)	(100)	(400)
Inc (loss) before taxes	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)	(46,817)	(45,590)	(44,362)	(42,521)	(178,291)
Income tax exp (benefit)										
NI as reported	(23,879)	(28,880)	(34,188)	(50,534)	(137,481)	(46,817)	(45,590)	(44,362)	(42,521)	(178,291)
EPS as reported	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	(\$1.25)	(\$1.21)	(\$1.06)	(\$1.01)	(\$4.76)
Adj-NI ex-1x items	(\$0.75)	(\$0.91)	(\$1.07)	(\$1.35)	(\$4.16)	(\$1.25)	(\$1.21)	(\$1.06)	(\$1.01)	(\$4.76)
Weighted avg. shares (000)	31,704	31,826	31,931	37,451	33,027	37,601	37,751	41,751	41,901	37,477
Fully diluted shares (000)	35,208	40,421	36,931	42,451	38,753	40,101	40,251	44,251	44,401	39,977

Source: Company Reports: Laidlaw & Company estimates

Figure 4: Annual Income Statement

Flexion Therapeutics							
Annual income statement							
(\$000 except per share)	2015A	2016A	2017A	2018E	2019E	2020E	Comments
Revenues							
Zilretta - OA pain			\$355	\$25,233	\$103,256	\$223,343	
Total Revenue	\$0	\$0	\$355	\$25,233	\$103,256	\$223,343	
Expenses:							
Cost of Revenue (COGS)	-	-	4	2,523	10,326	20,101	
Gross Margin	-	-	351	22,709	92,931	203,242	
R&D	32,691	41,314	51,231	70,000	80,000	90,000	
G&A	13,372	28,466	78,801	120,600	130,600	145,600	Self-launch Zilretta in US
Total op exp	46,063	69,780	130,032	190,600	210,600	235,600	
Inc/(loss) from Ops	(46,063)	(69,780)	(129,681)	(167,891)	(117,669)	(32,358)	
Int income (exp), net	675	(226)	(7,550)	(10,000)	(10,000)	(10,000)	
Other expenses, net	(927)	(1,887)	(250)	(400)	(500)	(500)	
Inc/(loss) before taxes	(46,315)	(71,893)	(137,481)	(178,291)	(128,169)	(42,858)	
Income tax exp (benefit)	-	-	-	-	-	(6,429)	
NI as reported	(\$46,315)	(\$71,893)	(\$137,481)	(\$178,291)	(\$128,169)	(\$36,429)	
EPS as reported	(\$2.15)	(\$2.84)					
Adj-EPS ex-1X items		(\$2.96)	(\$4.16)	(\$4.76)	(\$3.17)	(\$0.89)	
Weighted avg. shares (000)	21,497	25,296	33,027	37,477	40,450	40,950	
Fully diluted shares (000)	23,152	27,787	38,753	39,977	42,950	43,450	

Source: 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.

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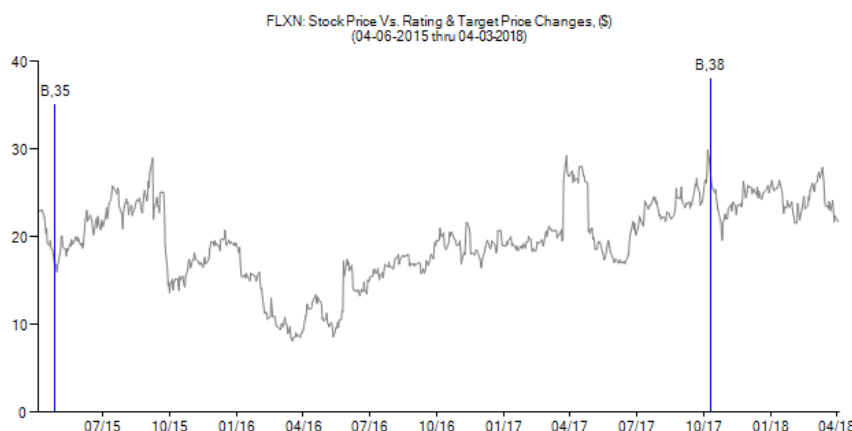
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Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price (\$)
04/28/...	Buy (B)	16.87

3 Year Price Change History

Date	Target Price (\$)	Closing Price. (\$)
04/28/...	35.00	16.87
10/10/...	38.00	27.17

Source: Laidlaw & Company

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			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.	64.71%	27.45%	3.92%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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