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USA | Healthcare | Biotechnology

October 31, 2014

Jefferies

BUY

Price target \$19.00 (from \$20.00)

Price \$7.00

GlycoMimetics, Inc. (GLYC) In-line Q3: Data From GMI-1271 PI In Healthy Volunteers In Q4'14

Key Takeaway

With in-line Q3, GLYC reported that dosing has been completed in healthy volunteers in GMI-1271 PI study with data due in Q4'14. Recently, GLYC reported that its partner Pfizer informed that rivipansel PIII in sickle cell disease will be delayed beyond 2014 due to drug formulations issues. We believe that it could be a 6-month delay in the initiation of PIII as we await further details.

GMI-1271 PI data from Healthy Volunteers in Q4'14: GLYC reported that dosing has been completed in healthy volunteer in the PI study evaluating GMI-1271, an E-selectin inhibitor, for acute myeloid leukemia. The first part of PI is measuring the safety and PK/ PD data of single ascending dose of GMI-1271 in healthy volunteers with data expected in Q4'14. Following favorable data, GLYC wants to initiate the PI/II study in AML pts in Q4'14 where safety and PK/PD will be studied with an effective dose range decided based on preclinical data. Preliminary data from the PI/II study is expected in mid-'15.

All Eyes on Rivipansel PIII Initiation: In September, GLYC reported that its partner, Pfizer (PFE, \$29.84, Buy), informed the company that the rivipansel PIII study that was supposed to initiate in H2'14 will be significantly delayed due to manufacturing issues with the drug formulation. Mgmt reported that while the drug for PIII was developed by GLYC, the technology of rivipansel development and formulation was transferred to PFE for PIII. GLYC believes that the issue is not with the active pharmaceutical ingredients (API) of rivipansel and it makes us believe that the manufacturing issues could be related to the changes made to develop clinical/commercial grade formulation of rivipansel for PIII. We currently believe that it could be a 6-month delay in the initiation of PIII as we await further details in coming months. The PIII study is evaluating rivipansel in treating vaso-occlusive crisis in ~300 SCD pts with time to discharge from hospital as 1 EP.

Q3 Financials: GLYC reported Q3 GAAP EPS of (\$0.35) (v. JEF est: \$0.70 and cons: (\$0.29)) due to delay in initiation of PIII trial of rivipansel. GLYC was supposed to receive \$20M milestone payment (JEF est) in Q3 upon initiation of rivipansel PIII. Op-Ex was slightly higher at \$6.7M (v. JEF est: \$5.8M) due to higher SG&A related to public company operations. Cash and equivs were \$61M at the end of Q3.

Valuation/Risks

We arrive at our \$19 PT (v. prev \$20) by using a DCF methodology. Risks include commercial, regulatory, and clinical.

USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)		4.0	35.0	15.0	3.1	23.1		25.0
EV/Rev		14.8x		3.9x		2.6x		2.4x
EPS								
Mar		(2.33)		(0.30)A				
Jun		(1.84)		0.39A				
Sep		(1.90)	0.70	(0.35)A				
Dec		(2.80)	(0.29)	(0.31)				
FY Dec		(8.87)	0.51	(0.56)	(1.42)	(0.58)		(0.02)
FY P/E		NM		NM		NM		NM

Financial Summary	
Net Debt (MM):	(\$61.4)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$61.4
Cash/Share:	\$3.25
Cash (MM):	\$61.4
Market Data	
52 Week Range:	\$18.99 - \$6.02
Total Entprs. Value (MM):	\$59.0
Market Cap. (MM):	\$120.4
Insider Ownership:	57.0%
Institutional Ownership:	43.0%
Shares Out. (MM):	17.2
Float (MM):	7.9
Avg. Daily Vol.:	31,731

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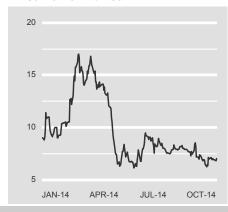
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Valuation

We arrive at our \$19 PT (v. prev \$20) based on a DCF valuation model which assumes a WACC of 12%, terminal growth rate of 0% and outstanding shares of 18.9 million, driven by potential U.S. sales of GMI-1070 and GMI-1271. We estimate unadjusted peak sales of \$1.6B (\$227M adjusted), and is derived from GMI-1070 (\$850M unadjusted; 77M risk-adjusted), and GMI-1271 (\$752 M unadjusted; 150M risk-adjusted). We estimate US approval and launch of GMI-1070 in 2018 and early 2020 for GMI-1271. We believe GMI-1070 to be approved in EU in late 2018. We have not have included EU sales of GMI-1271 in our model.

Exhibit 1: DCF sensitivity analysis

Discount rate	Price/Share
8.0%	\$27.26
10.0%	\$22.63
12.0%	\$19.00
14.0%	\$16.13
16.0%	\$13.85

Source: Jefferies estimates

Risks

Clinical Failure: As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

Regulatory Failure: The FDA could determine the new drug application is inadequate for GMI1070 and GMI-1271 and could delay approval. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

Commercial Failure: We currently project \$218 million (risk-adjusted) in peak U.S. sales for GMI-1070 and GMI-1271. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

Financing Risks: We expect the company to have adequate cash to 1H 2016. It may need additional financing(s) in 2016 and beyond to fund a potential U.S. launch of GMI-1070 and GMI-1271, and to fund R&D in additional indications.

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Exhibit 2: GlycoMimetics Income Statement

Glycomimetics

Quarterly Income Statement

	2011A	2012A	2013E			2014E			2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
	FY	FY	FY	1QA	2QA	3QA	4QE	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																		
GM I-1070 US Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.3	8.6	11.5	16.4	24.5	32.9	38
GM I-1070 EU Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.1	19	2.9	4.0	4.9	5
GM I-1271 Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	41.1	78.3	94.1	110.6	121
License and collaboration revenues	3.8	15.3	4.0	0.0	15.0	0.0	0.0	15.0	23.1	25.0	50.0	50.0	0.0	0.0	0.0	0.0	40.0	0
Total revenue, net	3.8	15.3	4.0	0.0	15.0	0.0	0.0	15.0	23.1	25.0	50.0	53.7	9.7	54.5	97.6	122.6	188.3	165.
Costs and expenses:																		
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.6	0.0	0.0	0.0	0.0	2.1	3.9	4.7	5.5	6
Research & development	7.8	9.4	11.7	3.9	5.4	5.1	5.2	19.5	26.8	22.5	21.9	19.3	20.3	20.9	215	22.1	22.8	23
Selling, general & administrative	2.1	2.2	2.9	1.2	1.6	1.6	0.7	5.1	2.6	2.8	3.0	3.3	3.4	8.6	8.9	9.1	9.4	9
Total operating expenses	9.9	11.6	14.6	5.1	7.0	6.7	5.9	24.7	34.0	25.3	24.9	22.6	23.7	31.5	34.3	36.0	37.7	39.
Income (loss) from operations	(6.1)	3.7	(10.6)	(5.1)	8.1	(6.7)	(5.9)	(9.6)	(10.9)	(0.3)	25.1	31.1	(14.0)	23.0	63.3	86.7	150.5	126.
Other income (expense):																		
Miscellaneous (expense) income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0
Interest expense	(0.0)	(0.0)	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0
Net profit (loss) before income taxes	(6.1)	3.7	(10.6)	(5.1)	8.1	(6.7)	(5.9)	(9.6)	(10.9)	(0.3)	25.1	31.1	(14.0)	23.0	63.3	86.7	150.5	126.
Income tax expense (benefit)					0.1	(0.1)		0.0			0.0	0.0	0.0	0.0	0.0	30.3	52.7	44
Income tax (%)											0.0%	0.0%	0.0%	0.0%	0.0%	35.0%	35.0%	35.0
Net Income (GAAP)	(6.1)	3.7	(10.6)	(5.1)	8.0	(6.7)	(5.9)	(9.6)	(10.9)	(0.3)	25.1	31.1	(14.0)	23.0	63.3	56.3	97.8	82.
EPS, GAAP																		
Basic	(6.79)	4.06	(8.87)	(0.30)	0.42	(0.35)	(0.31)	0.58	(0.58)	(0.02)	1.22	1.49	(0.66)	1.07	2.91	2.57	4.41	3.6
Diluted	\$ (6.79)	\$ 0.33	\$ (8.87)	\$ (0.30)	0.39	\$ (0.35)	\$ (0.31)	\$ (0.56)	\$ (0.58)	\$ (0.02)	\$ 1.22	\$ 1.49	\$ (0.66)	\$ 1.06	\$ 2.86	\$ 2.49	\$ 4.24	\$ 3.4
Weighted average share- Basic	0.9	0.9	12	17.2	18.8	18.9	18.9	18.5	18.9	19.9	20.5	20.9	21.3	21.5	21.7	21.9	22.2	2
Weighted average share- Diluted	0.9	11.0	12	17.2	20.2	18.9	18.9	18.8	18.9	19.9	20.5	20.9	21,3	21.7	22.2	22.6	23.1	2

Source: Jefferies estimates, company data

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Exhibit 3: GlycoMimetics DCF Analysis

Glycomimetics

Discounted Cash Flow Analysis

Unlevered free cash flow	1.7	(6.8)	(10.7)	(11.2)	(1.7)	26.6	29.1	(14.5)	22.0	62.3	55.4	96.9	82.0
(-): Changes in w orking capital	1.9	(3.8)	1.0	0.2	1.3	(1.5)	2.0	0.4	0.9	0.9	0.9	0.9	0.0
(-): Capital expenditures	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(+):FAS-123 Options	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(+):Depreciation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EBIAT	3.7	(10.6)	(9.6)	(10.9)	(0.3)	25.1	31.1	(14.0)	23.0	63.3	56.3	97.8	82.0
(-): Taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	30.3	52.7	44.2
EBIT	3.7	(10.6)	(9.6)	(10.9)	(0.3)	25.1	31.1	(14.0)	23.0	63.3	86.7	150.5	126.2
Operating Expenses	11.6	14.6	24.7	34.0	25.3	24.9	22.6	23.7	31.5	34.3	36.0	37.7	39.3
Sales	15.3	4.0	15.0	23.1	25.0	50.0	53.7	9.7	54.5	97.6	122.6	188.3	165.5
(All values in \$MM)	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E

Source: Jefferies estimates, company data

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Company Description

GlycoMimetics, Inc., a clinical stage biotechnology company, focuses on the discovery and development of glycomimetic drugs to address unmet medical needs resulting from diseases. Its lead product includes GMI-1070, a pan-selectin antagonist that has completed Phase II clinical trials for the treatment of vaso-occlusive crisis. The company is partnered with Pfizer on the development of GMI-1070. The company is also developing GMI-1271, a specific E-selectin antagonist, which it plans to initiate a Phase I clinical trials patients with acute myeloid leukemia and potentially other hematologic cancers. GlycoMimetics, Inc. was incorporated in 2003 and is headquartered in Gaithersburg, Maryland.

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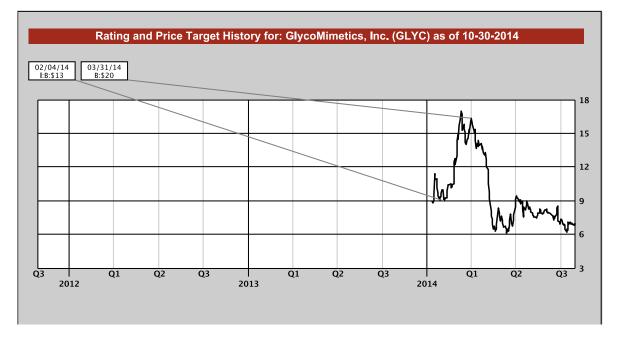
Risk which may impede the achievement of our Price Target

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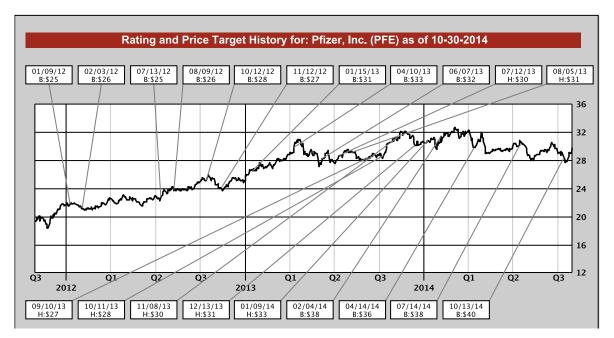
• GlycoMimetics, Inc. (GLYC: \$7.00, BUY)

• Pfizer, Inc. (PFE: \$29.84, BUY)



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