

COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

July 31, 2014

Jefferies

GlycoMimetics, Inc. (GLYC) Q2 In-line; GMI-1070 PIII to Initiate in '14

BUY

Price target \$20.00

Price \$8.46

Key Takeaway

With in-line Q2, GLYC expects PFE to initiate the 300-400 patient PIII trial testing GMI-1070 in sickle cell disease patients hospitalized due to vasoocclusive crises in H2'14 (JEF est: Q3'14). We continue to believe that PIII has 75% odds of success with US launch in 2017. In June, the first healthy volunteer was dosed in a PI trial for GMI-1271.

GMI-1070 Phase III Trial in H2'14: GLYC's reiterated that its partner, Pfizer (PFE, \$28.70, Buy), will initiate PIII trials for GMI-1070 for vaso-occlusive crisis in H2'14 (JEF est: Q3'14). Based on discussions with FDA, GLYC reported that time to discharge will be the 1 EP. In contrast the PII study of GMI-1070 had composite endpoints of mean resolution of vaso-occlusive crises, time to hospital discharge and reduction in the need for opioids and pain score, although the company did note a stronger benefit on time to hospital discharge in the PII trial. GLYC mentioned that the PIII trial may enroll 300 pts which is in-line with expectations. GLYC anticipates that it would take 2.5 years to complete enrollment in PIII. GLYC anticipates the remaining \$20M of the \$35M milestone will be received upon dosing of first pt in the PIII study. We estimate 75% odds of success in the GMI-1070 PIII study and expect data in H2'16 and potential approval in late '17.

GMI-1271 PI AML Initiated: In June, the first healthy volunteer was dosed in a PI study for GMI-1271, an E-selectin inhibitor, for acute myeloid leukemia. The first part of PI will involve measuring safety and PK/PD data of single ascending dose of GMI-1271 in healthy volunteers with data expected in H2'14. Following favorable data, GLYC wants to initiate the PI/II study in AML pts in H2'14 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.

Q2 Financials: GLYC reported Q2 GAAP EPS of \$0.39 (v. JEF est: \$0.57 and cons: \$0.24) on a \$15M payment from PFE under the collaboration for GMI-1070. R&D expenses were higher at \$5.4M (v. JEF est: \$4.5M) on advancement of GMI-1271 for AML, and a \$1.5M license fee payment to the University of Basel. Cash and equivs were \$66M at end Q2.

Valuation/Risks

We arrive at our \$20 PT by using a DCF methodology. Risks to our estimates include clinical trial failure, regulatory approval risks and commercial launch risks.

USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	4.0	--	35.0	--	3.1	--	25.0
EV/Rev		19.8x		2.3x		25.6x		3.2x
EPS								
Mar	--	(2.33)	--	(0.30)A	--	--	--	--
Jun	--	(1.84)	0.57	0.39A	--	--	--	--
Sep	--	(1.90)	0.83	0.70	--	--	--	--
Dec	--	(2.80)	(0.34)	(0.29)	--	--	--	--
FY Dec	--	(8.87)	0.77	0.51	(1.52)	(1.42)	--	(0.02)
FY P/E		NM		16.6x		NM		NM

Financial Summary

Net Debt (MM):	(\$66.2)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$66.2
Cash/Share:	\$3.28
Cash (MM):	\$66.2

Market Data

52 Week Range:	\$18.99 - \$6.02
Total Entprs. Value (MM):	\$79.3
Market Cap. (MM):	\$145.5
Insider Ownership:	57.0%
Institutional Ownership:	43.0%
Shares Out. (MM):	17.2
Float (MM):	7.8
Avg. Daily Vol.:	138,660

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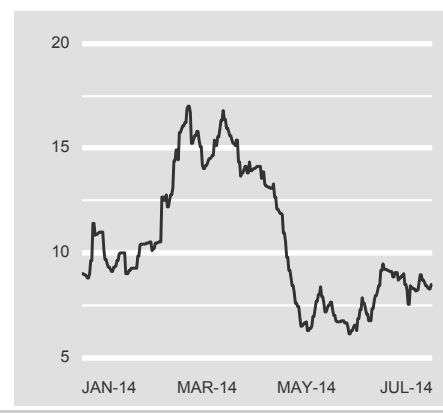
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Price Performance



Valuation

We arrive at our \$20 PT based on a DCF valuation model which assumes a WACC of 12%, terminal growth rate of 0% and outstanding shares of 18.6 million, driven by potential U.S. sales of GMI-1070 and GMI-1271. We estimate unadjusted peak sales of \$1.4B (\$234M adjusted), and is derived from GMI-1070 (\$637M unadjusted; 77M risk-adjusted), and GMI-1271 (\$752 M unadjusted; 157M risk-adjusted). We estimate US approval and launch of GMI-1070 in H2 2017 and early 2020 for GMI-1271. We believe GMI-1070 to be approved in EU in early 2018. We have not have included EU sales of GMI-1271 in our model.

Exhibit 1: DCF sensitivity analysis

Discount rate	Price/Share
6.0%	\$34.92
8.0%	\$28.84
10.0%	\$24.11
12.0%	\$20.40
14.0%	\$17.46
16.0%	\$15.12

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 \$152 million (risk-adjusted) in 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.

Exhibit 2: Key Upcoming Milestones.

Product	Indication	Event	Date
GMI-1070	Sickle cell pain crisis	<i>End of PII meeting with FDA and development of PIII design</i>	<i>Q1 2014</i>
		Initiation of PIII trial for vaso occlusion pain crisis in sickle cell disease	H2 2014
		Completion of enrollment for PIII trial	H1 2016
		Data readout from the PIII study	H2 2016
		US approval	H2 2017
		EU approval	H1 2018
GMI-1271	Acute myeloid leukemia	<i>IND filing</i>	<i>Q1 2014</i>
		<i>Initiation of Phase I</i>	<i>Q2 2014</i>
		Phase I data read-out from healthy volunteers	H2 2014
		Initiation of PIb/II	YE 2014

Source: Company estimates, Jefferies.

Exhibit 3: GlycoMimetics Income Statement

Glycomimetics

Quarterly Income Statement

(All values in \$MM except EPS and average shares)

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	2011A	2012A	2013E	2014E				2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E	
	FY	FY	FY	1Q4	2Q4	3Q4	4Q4	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	
Revenue:																										
GM1-1070 US Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	12	6.7	12.1	16.8	22.9	28.9	35.7	42.2	47.5	53.3	58.3	61.2	64.3	67.6	14	15	
GM1-1070 EU Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.1	1.8	2.9	4.0	4.9	5.6	6.3	7.1	7.5	7.8	8.2	8.9	0.5	0.2	
GM1-1271 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	41.1	78.3	94.1	106.6	121.7	127.1	132.8	138.6	144.5	147.4	150.4	153.4	156.5	
License and collaboration revenues	3.8	15.3	4.0	0.0	0.0	0.0	0.0	35.0	3.1	25.0	50.0	50.0	0.0	0.0	0.0	40.0	0.0	0.0	0.0	0.0	0.0	40.0	0.0	0.0	0.0	
Total revenue, net	3.8	15.3	4.0	0.0	0.0	0.0	0.0	35.0	3.1	25.0	51.2	57.0	13.3	59.8	104.1	127.0	191.1	169.5	181.0	193.1	204.3	213.6	260.0	226.8	155.3	158.2
Costs and expenses:																										
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0	0.0	0.0	0.0	2.1	3.9	4.7	5.5	6.1	6.4	6.6	6.9	7.2	7.4	7.5	7.7	7.8	
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	22.1	22.8	23.5	24.0	24.4	24.9	25.4	25.9	26.2	26.5	26.7	
Selling, general & administrative	2.1	2.2	2.9	1.2	1.6	0.7	0.7	4.1	2.6	2.8	3.0	3.3	3.4	3.6	3.9	4.1	4.2	4.3	4.4	4.5	4.6	4.7	4.8	4.9	5.0	
Total operating expenses	9.9	11.6	14.6	5.1	7.0	5.8	5.9	23.7	30.0	25.3	24.9	22.6	23.7	24.5	26.0	27.7	28.3	28.4	28.9	29.4	29.9	30.4	30.9	31.4	31.9	
Income (loss) from operations	(6.1)	3.7	(10.6)	(5.1)	8.1	14.3	(5.9)	11.4	(26.9)	(0.3)	26.3	34.5	(10.5)	28.3	69.9	91.0	153.3	139.2	140.7	151.8	161.9	170.1	215.5	191.5	109.2	111.4
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	0.0	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	0.0	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	0.0	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	14.3	(5.9)	11.4	(26.9)	(0.3)	26.3	34.5	(10.5)	28.3	69.9	91.0	153.3	139.2	140.7	151.8	161.9	170.1	215.5	191.5	109.2	111.4
Income tax expense (benefit)					0.1			0.1			0.0	0.0	0.0	0.0	0.0	0.0	31.9	53.7	45.6	49.2	53.1	56.7	59.5	75.4	63.5	38.2
Income tax (%)					0.1			0.1			0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%	35.0%
Net income (GAAP)	(6.1)	3.7	(10.6)	(5.1)	8.0	14.3	(5.9)	11.3	(26.9)	(0.3)	26.3	34.5	(10.5)	28.3	69.9	59.2	99.7	84.6	91.4	98.6	105.2	110.5	140.0	118.0	71.0	72.4
EPS, GAAP																										
Basic	(6.79)	4.06	(8.87)	(0.30)	0.42	0.76	(0.31)	0.58	(14.2)	(0.02)	1.29	1.65	(0.49)	1.32	3.22	2.70	4.50	3.79	4.05	4.33	4.57	4.75	5.96	4.87	2.96	2.99
Diluted	(6.79)	4.03	(8.87)	(0.30)	0.39	0.76	(0.29)	0.51	(14.2)	(0.02)	1.29	1.65	(0.49)	1.30	3.16	2.62	4.33	3.60	3.82	4.04	4.22	4.35	5.40	4.46	2.63	2.63
Weighted average share-Basic	0.9	12	12	12	17.2	18.8	18.8	18.9	18.9	19.8	20.4	20.9	21.3	21.5	21.7	21.9	22.1	22.2	22.6	22.8	23.0	23.3	23.7	24.0	24.2	24.2
Weighted average share-Diluted	0.9	110	12	17.2	20.2	20.3	20.3	19.5	19.9	19.8	20.4	20.9	21.3	21.7	22.1	22.6	23.0	23.5	24.0	24.4	24.9	25.4	25.9	26.4	27.0	27.5

Source: Company data and Jefferies estimate

Source: Jefferies estimates, company data

Exhibit 4: GlycoMimetics DCF Analysis**Glycomimetics****Discounted Cash Flow Analysis**

(All values in \$MM)	2012A	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E
Sales	15.3	4.0	35.0	3.1	25.0	51.2	57.0	13.3	59.8	104.1	127.0	191.1	169.5	181.0	193.1	204.3	213.6	260.0	226.8	155.3	158.2
Operating Expenses	11.6	14.6	23.7	30.0	25.3	24.9	22.6	23.7	31.5	34.3	36.0	37.7	39.3	40.3	41.4	42.4	43.6	44.5	45.3	46.0	46.8
EBIT	3.7	(10.6)	11.4	(26.9)	(0.3)	26.3	34.5	(10.5)	28.3	69.9	91.0	153.3	130.2	140.7	151.8	161.9	170.1	215.5	181.5	109.2	111.4
(-): Taxes	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	31.9	53.7	45.6	49.2	53.1	56.7	59.5	75.4	63.5	38.2	39.0	
EBIAT	3.7	(10.6)	11.3	(26.9)	(0.3)	26.3	34.5	(10.5)	28.3	69.9	59.2	99.7	84.6	91.4	98.6	105.2	110.5	140.0	118.0	71.0	72.4
(+):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	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(-): Changes in working 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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Unlevered free cash flow	1.7	(6.8)	10.3	(27.2)	(1.7)	27.8	32.4	(10.9)	27.3	68.9	58.2	98.7	84.6	91.4	98.6	105.2	110.5	140.0	118.0	71.0	72.4

Source: Jefferies estimates, company data

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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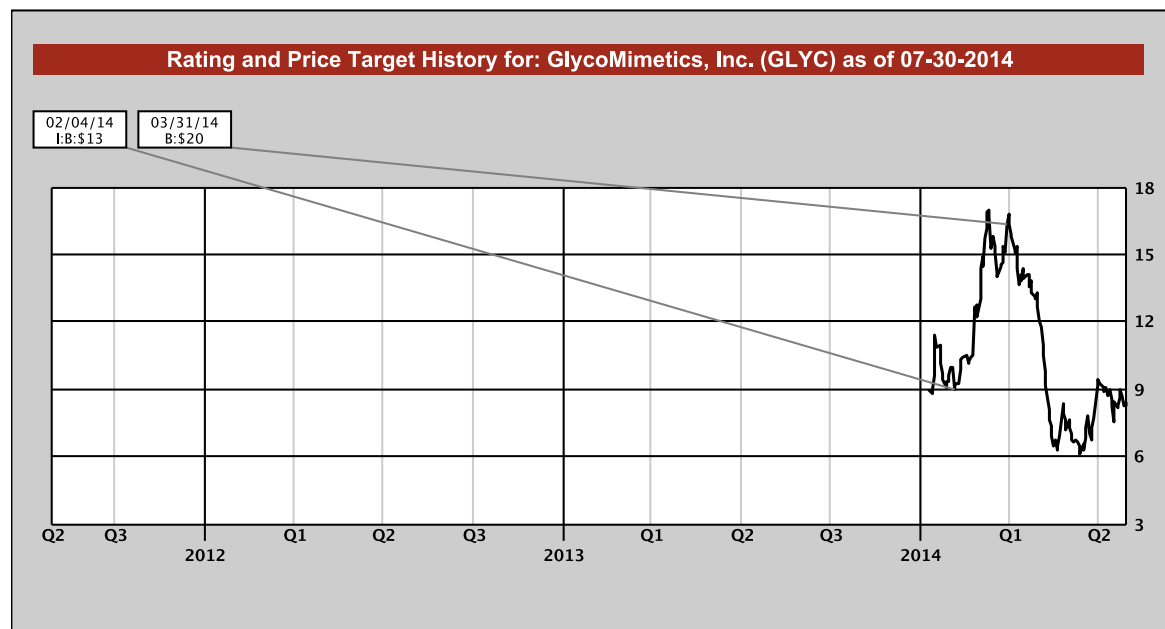
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