

## COMPANY NOTE

Target Change

USA | Healthcare | Biotechnology

March 31, 2014

# Jefferies

## GlycoMimetics, Inc. (GLYC) GMI-1271 Phase I To Initiate In Q2 2014

### Key Takeaway

**With in-line Q4, we expect GLYC to initiate the Phase I trial of GMI-1271 in acute myeloid leukemia in Q2'14. We expect GLYC's partner Pfizer to initiate the 300-400 patient Phase III trials testing GMI-1070 in sickle cell disease patients hospitalized due to vaso-occlusive crises in Q3 2014. We believe the Phase III has 75% odds of success with US launch in 2017.**

**GMI-1271 PI In AML In Q2 2014:** GMI-1271, an E-selectin inhibitor, will initiate Phase I trials in acute myeloid leukemia in Q2'14 based on supportive preclinical data. Preclinical data reported reductions in tumor volume by 50-67% when combined with chemotherapy vs chemotherapy alone. E-selectin are found to be overexpressed in both solid and hematopoietic malignancies including acute myeloid leukemia (AML). E-selectin has been suggested as one of the factors responsible for metastasis of cancers.

**GMI-1070 Phase III Trial In Q3:** We believe GLYC's partner, Pfizer (PFE, \$32.12, Buy), will initiate Phase III trials for GMI-1070 in patients with vaso-occlusive crises in Q3 2014. We currently estimate 75% odds of success and estimate at a minimum the Phase III would need to be sized between 300-400 patients to achieve statistical significance with a more conservative 30-hour improvement in resolution of vaso-occlusive crises. The Phase II data showed clinically meaningful improvements in resolution of vaso-occlusive crises by a mean of 40 hours, time to hospital discharge by more than 2 days, and 80% reduction in the need for opioids. We anticipate it would take 2 years to complete patient enrollment, and expect data in 2H'16 and potential market approval in late '17.

**Q4 Financials:** GLYC reported FY'13 EPS of (\$8.87) v. FY'12 of \$0.33. Cash and equivs were \$2.3M at end Q4, and including the net proceeds of \$57M from the IPO in Jan '14, and should be sufficient to fund operations through to end of '15.

### Valuation/Risks

We arrive at our \$20 PT (v. prev \$13) by using a DCF methodology. Anticipating the GMI-1271 PI trial in Q2'14, we have reduced our risk discount for '1271 from 90% to 80%. 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)	5.2	4.0	--	35.0	--	3.1	--	25.0
EV/Rev		55.0x		6.3x		71.0x		8.8x
<b>EPS</b>								
Mar	(2.18)	(2.33)	--	(0.24)	--	--	--	--
Jun	(2.16)	(1.84)	--	(0.28)	--	--	--	--
Sep	(2.09)	(1.90)	--	1.57	--	--	--	--
Dec	(0.22)	(2.80)	--	(0.31)	--	--	--	--
FY Dec	(6.65)	(8.87)	--	0.74	--	(1.41)	--	(0.02)
FY P/E		NM		20.4x		NM		NM

**BUY**

Price target \$20.00

(from \$13.00)

Price \$15.10

### Financial Summary

Net Debt (MM):	(\$60.9)
Long-Term Debt (MM):	\$0.0
Cash & ST Invest. (MM):	\$60.9
Cash/Share:	\$3.27
Cash (MM):	\$60.9

### Market Data

52 Week Range:	\$18.99 - \$8.40
Total Entprs. Value (MM):	\$220.0
Market Cap. (MM):	\$280.9
Insider Ownership:	57.0%
Institutional Ownership:	43.0%
Shares Out. (MM):	18.6
Float (MM):	7.1
Avg. Daily Vol.:	NA

**Biren Amin \***

Equity Analyst

(212) 284-8162 bamin@jefferies.com

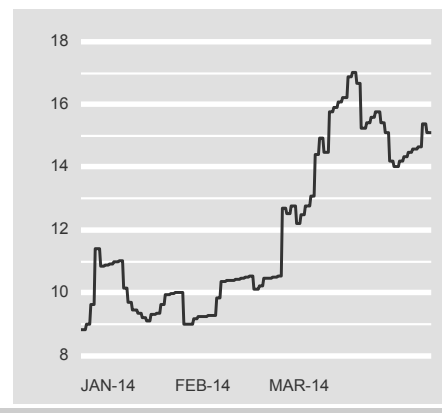
**Hugo Ong, Ph.D. \***

Equity Associate

(212) 323-3364 hong@jefferies.com

\* Jefferies LLC

### Price Performance



**GLYC**

Target Change

March 31, 2014

GlycoMimetics, Inc.

**Buy: \$20 Price Target****Scenarios****Target Investment Thesis**

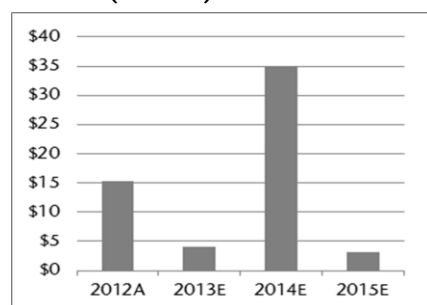
- Positive outcome in GMI-1070's PIII study for sickle cell pain crisis, with US approval in H2' 2017 and EU approval in early 2018
- GMI-1070 expected to have peak sales of \$563M (risk-adjusted) in US and \$74M risk-adjusted) in EU
- U.S. regulatory approval of GMI-1271 in AML in 2020 with peak sales of \$782M (risk-unadjusted)
- DCF-based PT: \$20

**Upside Scenario**

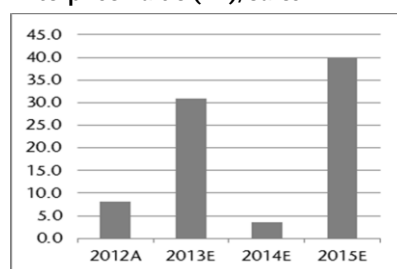
- Positive expansion of GMI-1271 and GMI-1070 into other blood disorders.
- DCF-based PT: \$29

**Downside Scenario**

- Negative outcome in GMI-1070 PIII study, DCF-based PT: \$2
- Negative outcome in GMI-1271 clinical program, DCF-based PT: \$6

**Long Term Analysis****Revenue (millions)**

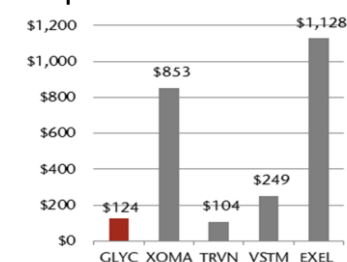
Source: Company data; Jefferies estimates

**Enterprise Value (EV)/Sales**

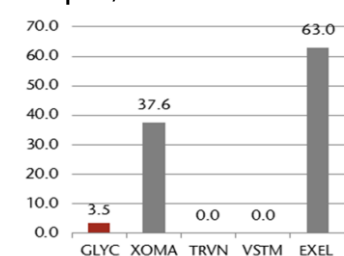
Source: Company data; Jefferies estimates

**Other Considerations**

We consider small-cap and mid-cap biotech companies with late-stage programs to continue to be attractive targets for partnering or M&A partnering with large-cap biotech and pharma companies, which we believe will be a driving factor for performance in the biotech sector 2013-2014.

**Peer Group****Group EV**

Source: Factset, Jefferies estimates

**Group EV/2013E Sales**

Source: Factset, Jefferies estimates

**Recommendation / Price Target**

Ticker	Rec.	PT
<b>GLYC</b>	<b>Buy</b>	<b>\$20</b>
XOMA	Buy	\$9
TRVN	Buy	\$11
VSTM	Buy	\$21
EXEL	Hold	\$6

**Catalysts**

- Initiation of GMI-1070 PIII in H1' 2014
- IND filing for GMI-1271 in Q1' 14 and initiation of PI in AML in H1' 2014
- Preliminary data from GMI-1271 PI in AML in H2' 2014
- Initiation of Plb/II of GMI-1271 in AML in H2' 2014

**Company Description**

GlycoMimetics is a biotechnology company that is developing inhibitors that target the complex carbohydrates involved in multiple human diseases. GlycoMimetics develops its inhibitors by mimicking the interaction of these complex carbohydrates interactions with proteins. GlycoMimetics's lead product is GMI-1070, which is a pan-selectin inhibitor that will soon undergo critical phase III evaluation in sickle cell pain crisis. GlycoMimetics's pipeline also includes GMI-1271; an E-selectin inhibitor targeting acute myeloid leukemia, GMI-1050; a lectin inhibitor targeting pseudomonas infections and a dual E-selectin & CXCR4 antagonist targeting multiple cancers.

## Valuation

We arrive at our \$20 PT (v. prev \$13) 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
8.0%	\$28.68
10.0%	\$23.95
<b>12.0%</b>	<b>\$20.24</b>
14.0%	\$17.30
16.0%	\$14.96

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.**

<b>Product</b>	<b>Indication</b>	<b>Event</b>	<b>Date</b>
<b>GMI-1070</b>	<b>Sickle cell pain crisis</b>	End of PII meeting with FDA and development of PIII design	Q1 2014
		Initiation of PIII trial for vaso occlusion pain crisis in sickle cell disease	H1 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
<b>GMI-1271</b>	<b>Acute myeloid leukemia</b>	IND filing	Q1 2014
		Initiation of Phase I	H1 2014
		Phase I data read-out from healthy volunteers	H2 2014
		Initiation of PIIb/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)

(\$ in \$MM except EPS and average shares)																																
	2011A	2012A	2013E				2014E				2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E	2032E				
	FY	FY	1Q	2Q	3Q	4Q	FY	1Q	2Q	3Q	4Q	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY				
Revenue:																																
GM1-K70 US Royalties	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	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-K70 EU Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	1.1	1.9	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-K71 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	0.0	0.0	0.0	41.1	78.3	94.1	10.6	12.1	12.1	12.8	13.6	14.5	14.4	15.4	15.3	15.5			
License and collaboration revenues	3.8	6.3	12	12	12	0.8	0.1	4.0	0.0	35.0	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	0.0	0.0	0.0	0.0	0.0		
Total revenue, net	3.8	15.3	1.2	12	12	0.8	0.1	4.9	0.0	6.0	6.0	35.0	0.0	35.0	3.1	25.0	51.2	57.0	13.3	59.8	104.1	127.0	191.1	199.5	191.0	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	0.0	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	2.9	2.9	2.9	2.9	3.0	11.7	3.9	4.5	5.1	5.2	18.7	26.8	22.5	21.9	19.3	20.3	20.9	21.5	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	0.7	0.7	0.6	0.9	2.9	0.7	0.7	0.7	0.7	2.6	2.6	2.8	3.0	3.3	3.4	8.6	8.9	9.1	9.4	9.7	10.0	10.3	10.6	10.9	11.2	11.6	11.9	12.3		
Total operating expenses	9.9	11.6	3.6	3.6	3.5	3.9	14.6	4.6	5.2	5.8	5.9	21.3	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		
Income (loss) from operations	(6.1)	3.7	(2.4)	(2.4)	(2.7)	(3.9)	(10.6)	(4.6)	(5.2)	29.3	(5.9)	13.7	(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		
Other income (expense):																																
Miscellaneous (expense) 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	0.1	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	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	0.0	0.0	0.0	0.0	0.0		
Net profit (loss) before income taxes	(6.1)	3.7	(2.4)	(2.3)	(2.7)	(3.8)	(10.6)	(4.5)	(5.1)	29.3	(5.9)	13.8	(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		
Income tax expense (benefit)															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%	35.0%	35.0%		
Net income (GAAP)	(6.1)	3.7	(2.4)	(2.3)	(2.7)	(3.9)	(10.6)	(4.5)	(5.1)	29.3	(5.9)	13.8	(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	(6.78)	4.06	(2.33)	(1.84)	(1.90)	(2.80)	(8.87)	(0.24)	(0.28)	15.7	(0.31)	0.74	(14.1)	(0.02)	12.7	16.4	(0.49)	13.0	3.19	2.67	4.46	3.75	4.01	4.28	4.52	4.70	5.90	4.92	2.93	2.96		
Diluted	\$ (6.79)	\$ 0.33	\$ (2.33)	\$ (1.84)	\$ (1.90)	\$ (2.80)	\$ (8.87)	\$ (0.24)	\$ (0.28)	\$ 15.7	\$ (0.31)	\$ 0.74	\$ (14.1)	\$ (0.02)	\$ 12.7	\$ 16.4	\$ (0.49)	\$ 12.9	\$ 3.12	\$ 2.59	\$ 4.29	\$ 3.57	\$ 3.78	\$ 4.00	\$ 4.18	\$ 4.30	\$ 5.35	\$ 4.42	\$ 2.61	\$ 2.60		
Weighted average share- Basic	0.9	110	10	13	14	14	12	12.1	12.1	12.1	12.1	12.1	12.1	12.1	20.1	20.7	21.1	21.5	21.9	22.1	22.4	22.6	22.8	23.0	23.3	23.7	24.2	24.7	25.2	25.7	26.2	
Weighted average share- Diluted	0.9	110	10	13	14	14	12	12.1	12.1	12.1	12.1	12.1	12.1	12.1	20.1	20.7	21.1	21.5	21.9	22.4	22.8	23.3	23.7	24.2	24.7	25.2	25.7	26.2	26.7	27.3	27.8	

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	21.3	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)	13.7	(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	0.0	0.0	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)	13.7	(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)	12.7	(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

## Exhibit 5: GMI-1271 Revenue Build for Acute Myeloid Leukemia

GMI-1271	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032
U.S.																		
Total Net Sales of GMI-1271 in AML (\$M)				\$0.0	\$0.0	\$205.6	\$391.5	\$470.6	\$552.8	\$608.3	\$635.6	\$663.8	\$692.8	\$722.7	\$737.2	\$751.9	\$766.9	\$782.3
Risk discount																		
Total Net Sales of GMI-1271 in AML - risk adj. (\$M)				\$0.0	\$0.0	\$41.1	\$78.3	\$94.1	\$110.6	\$121.7	\$127.1	\$132.8	\$138.6	\$144.5	\$147.4	\$150.4	\$153.4	\$156.5
Total Net Sales of GMI-1271 in sickle cell crisis - risk adj. (\$M)				\$0.0	\$0.0	\$41.1	\$78.3	\$94.1	\$110.6	\$121.7	\$127.1	\$132.8	\$138.6	\$144.5	\$147.4	\$150.4	\$153.4	\$156.5
U.S. AML Market Opportunity																		
Total no. of AML patients (000's)	19,100	19,482	19,872	20,269	20,674	21,088	21,510	21,940	22,379	22,826	23,283	23,748	24,223	24,708	25,202	25,706	26,220	26,745
Relapsed/refractory prevalence	6,017	6,137	6,260	6,385	6,512	6,643	6,776	6,911	7,049	7,190	7,334	7,481	7,630	7,783	7,939	8,097	8,259	8,425
Elderly 1st line eligible prevalence	5,291	5,455	5,624	5,777	5,934	6,116	6,238	6,363	6,490	6,620	6,752	6,887	7,025	7,165	7,309	7,455	7,604	7,756
Elderly 1st line ineligible prevalence	3,495	3,565	3,637	3,709	3,783	3,859	3,936	4,015	4,095	4,177	4,261	4,346	4,433	4,522	4,612	4,704	4,798	4,894
Non-elderly 1st line prevalence	4,202	4,286	4,372	4,459	4,548	4,639	4,732	4,827	4,923	5,022	5,122	5,225	5,329	5,436	5,544	5,655	5,768	5,884
Patients on GMI-1271 (000's)						3,163	6,023	7,240	8,504	9,359	9,779	10,212	10,658	11,119	11,341	11,568	11,799	12,035
% market share						15.0%	28.0%	33.0%	38.0%	41.0%	42.0%	43.0%	44.0%	45.0%	45.0%	45.0%	45.0%	45.0%
U.S. Net Sales of GMI-1271 (\$M)						\$205.6	\$391.5	\$470.6	\$552.8	\$608.3	\$635.6	\$663.8	\$692.8	\$722.7	\$737.2	\$751.9	\$766.9	\$782.3
Risk discount																		
U.S. Net Sales of GMI-1271 - risk adj. (\$M)						\$205.6	\$391.5	\$470.6	\$552.8	\$608.3	\$635.6	\$663.8	\$692.8	\$722.7	\$737.2	\$751.9	\$766.9	\$782.3
Assumptions																		
Total treatment price (net)						\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000	\$65,000

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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The expected total return (price appreciation plus yield) for Buy rated stocks with an average stock price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% within a 12-month period.

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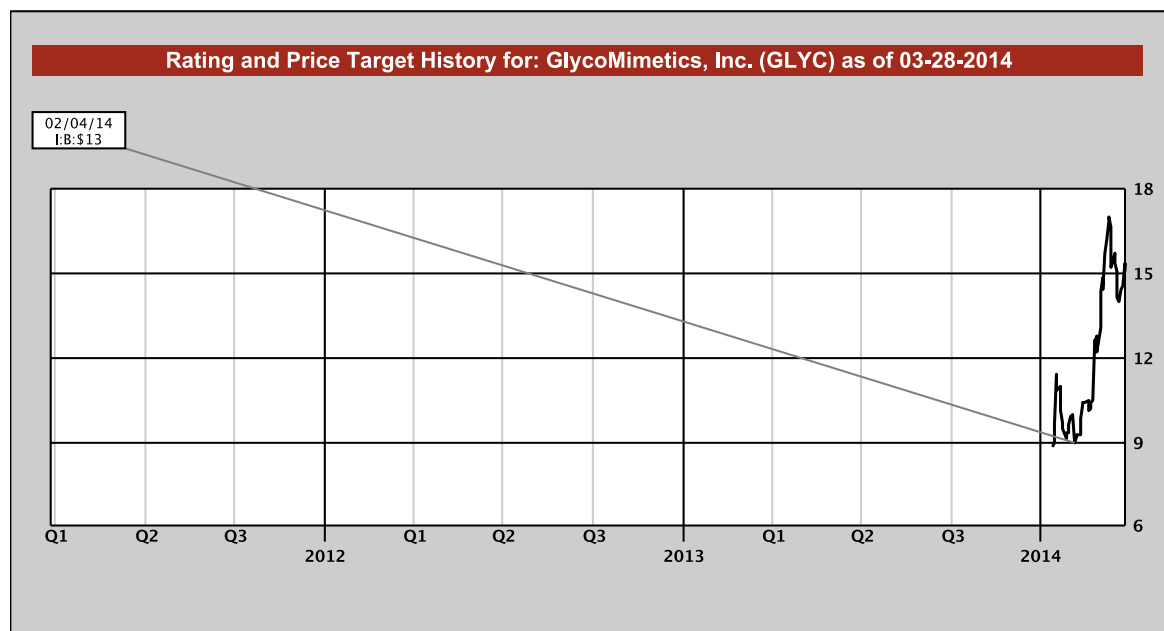
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- Pfizer, Inc. (PFE: \$31.88, BUY)
- Trevena, Inc. (TRVN: \$7.45, BUY)
- Verastem Inc. (VSTM: \$10.36, BUY)
- XOMA Ltd. (XOMA: \$4.96, BUY)



## Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY	891	49.15%	226	25.36%
HOLD	772	42.58%	136	17.62%
UNDERPERFORM	150	8.27%	5	3.33%



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