

COMPANY NOTE

Estimate Change

USA | Healthcare | Biotechnology

May 8, 2014

Jefferies

GlycoMimetics, Inc. (GLYC) In-Line Q1: GMI-1070 PIII To Initiate in Q3 2014

Key Takeaway

With in-line Q1, GLYC expects Pfizer to initiate the 300-400 patient Phase III trial testing GMI-1070 in sickle cell disease patients hospitalized due to vaso-occlusive crises in H2'14 (JEF est: Q3'14). We continue to believe that Phase III has 75% odds of success with US launch in 2017. GLYC suggested that it plans to initiate the Phase I trial of GMI-1271 in acute myeloid leukemia before the end of Q2'14.

GMI-1070 Phase III Trial in Q3: GLYC's suggested that its partner, Pfizer (PFE, \$29.02, Buy), will initiate Phase III trials for GMI-1070 in patients with vaso-occlusive crises in H2'14 (JEF est: Q3'14). As per agreement, since Pfizer didn't dose the first patient by April 2014, GLYC expects to receive the advance payment of \$15M in Q2'14 against the \$35M milestone payment to be received upon initiation of PIII trial. We currently estimate 75% odds of success and estimate 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.

GMI-1271 PI In AML In Q2 2014: Mgmt suggested that it will initiate the PI trial of GMI-1271, an E-selectin inhibitor in acute myeloid leukemia by end of 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.

Q1 Financials: GLYC reported Q1 GAAP EPS of (\$0.30) (v. JEF est: (\$0.24) and cons: (\$0.28), owing to higher op-ex. Cash and equivs were \$57M at end Q1, should be sufficient to fund operations through to end of '15.

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 | | 27.8x | | 3.2x | | 35.9x | | 4.4x |
| EPS | | | | | | | | |
| Mar | -- | (2.33) | (0.24) | (0.30)A | -- | -- | -- | -- |
| Jun | -- | (1.84) | (0.28) | 0.57 | -- | -- | -- | -- |
| Sep | -- | (1.90) | 1.57 | 0.83 | -- | -- | -- | -- |
| Dec | -- | (2.80) | (0.31) | (0.34) | -- | -- | -- | -- |
| FY Dec | -- | (8.87) | 0.74 | 0.77 | (1.41) | (1.52) | -- | (0.02) |
| FY P/E | | NM | | 12.7x | | NM | | NM |

BUY

Price target \$20.00

Price \$9.78

Financial Summary

| | |
|-------------------------|----------|
| Net Debt (MM): | (\$57.0) |
| Long-Term Debt (MM): | \$0.0 |
| Cash & ST Invest. (MM): | \$57.0 |
| Cash/Share: | \$3.31 |
| Cash (MM): | \$57.0 |

Market Data

| | |
|---------------------------|------------------|
| 52 Week Range: | \$18.99 - \$8.40 |
| Total Entprs. Value (MM): | \$111.2 |
| Market Cap. (MM): | \$168.2 |
| Insider Ownership: | 57.0% |
| Institutional Ownership: | 43.0% |
| Shares Out. (MM): | 17.2 |
| Float (MM): | 7.0 |
| Avg. Daily Vol.: | 143,816 |

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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 |
|---------------|----------------|
| 8.0% | \$28.44 |
| 10.0% | \$23.71 |
| 12.0% | \$20.00 |
| 14.0% | \$17.06 |
| 16.0% | \$14.72 |

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 | 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 | 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 | IND filing | Q1 2014 |
| | | Initiation of Phase I | Q2 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)

| (All values 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 | FY | 1Q4 | 2Q4 | 3Q4 | 4Q4 | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | FY | |
| Revenue: | | | | | | | | | | | | | | | | | | | | | | | | | | |
| GM+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 | |
| GM+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 | 1.9 | 2.9 | 4.0 | 4.9 | 5.6 | 6.3 | 7.1 | 7.5 | 7.8 | 8.2 | 8.9 | 0.5 | 0.2 | |
| GM+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 | 121 | 127 | 138 | 186 | 144.5 | 147.4 | 150.4 | 153.4 | 156.5 | |
| License and collaboration revenues | 3.8 | 15.3 | 4.0 | 0.0 | 15.0 | 20.0 | 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 | 15.0 | 20.0 | 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 | 226.0 | 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 | 0.6 | 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 | 4.5 | 5.1 | 5.2 | 16.7 | 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 | 2.9 | 1.2 | 0.7 | 0.7 | 0.7 | 3.2 | 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 | 14.6 | 5.1 | 5.2 | 5.8 | 5.9 | 21.9 | 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 | (10.6) | (5.1) | 9.9 | 14.3 | (5.9) | 13.1 | (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 | 0.1 | 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 | 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 |
| 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 |
| Net profit (loss) before income taxes | (6.1) | 3.7 | (10.6) | (5.1) | 9.9 | 14.3 | (5.9) | 13.2 | (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 | 0.0 | 31.9 | 53.7 | 45.6 | 49.2 | 53.1 | 56.7 | 59.5 | 75.4 | 63.5 | 38.2 | 39.0 |
| Income tax (%) | | | | | | | | | | | 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% | 35.0% |
| Net Income (GAAP) | (6.1) | 3.7 | (10.6) | (5.1) | 9.9 | 14.3 | (5.9) | 13.2 | (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) | 0.57 | 0.83 | (0.34) | 0.77 | (1.52) | (0.02) | 1.38 | 1.77 | (0.53) | 1.41 | 3.45 | 2.89 | 4.82 | 4.05 | 4.33 | 4.63 | 4.89 | 5.08 | 6.38 | 5.32 | 3.17 | 3.20 |
| Diluted | \$ (6.79) | \$ 0.33 | \$ (8.87) | \$ (0.30) | \$ 0.57 | \$ 0.83 | \$ (0.34) | \$ 0.77 | \$ (1.52) | \$ (0.02) | \$ 1.38 | \$ 1.77 | \$ (0.53) | \$ 1.40 | \$ 3.38 | \$ 2.81 | \$ 4.63 | \$ 3.86 | \$ 4.09 | \$ 4.32 | \$ 4.52 | \$ 4.65 | \$ 5.78 | \$ 4.77 | \$ 2.82 | \$ 2.82 |
| Weighted average share-Basic | 0.9 | 0.9 | 12 | 17.2 | 17.2 | 17.2 | 17.3 | 17.2 | 17.7 | 16.5 | 16.1 | 16.5 | 16.9 | 20.1 | 20.3 | 20.5 | 20.7 | 20.9 | 21.1 | 21.3 | 21.5 | 21.7 | 22.0 | 22.2 | 22.4 | 22.6 |
| Weighted average share-Diluted | 0.9 | 11.0 | 12 | 17.2 | 17.2 | 17.2 | 17.3 | 17.2 | 17.7 | 16.5 | 16.1 | 16.5 | 16.9 | 20.3 | 20.7 | 21.1 | 21.5 | 21.9 | 22.4 | 22.8 | 23.3 | 23.8 | 24.2 | 24.7 | 25.2 | 25.7 |

Source: Jefferies estimates, company data

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

| <i>(All values in \$MM)</i> | 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 | 21.9 | 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) | 13.1 | (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) | 13.1 | (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) | 12.1 | (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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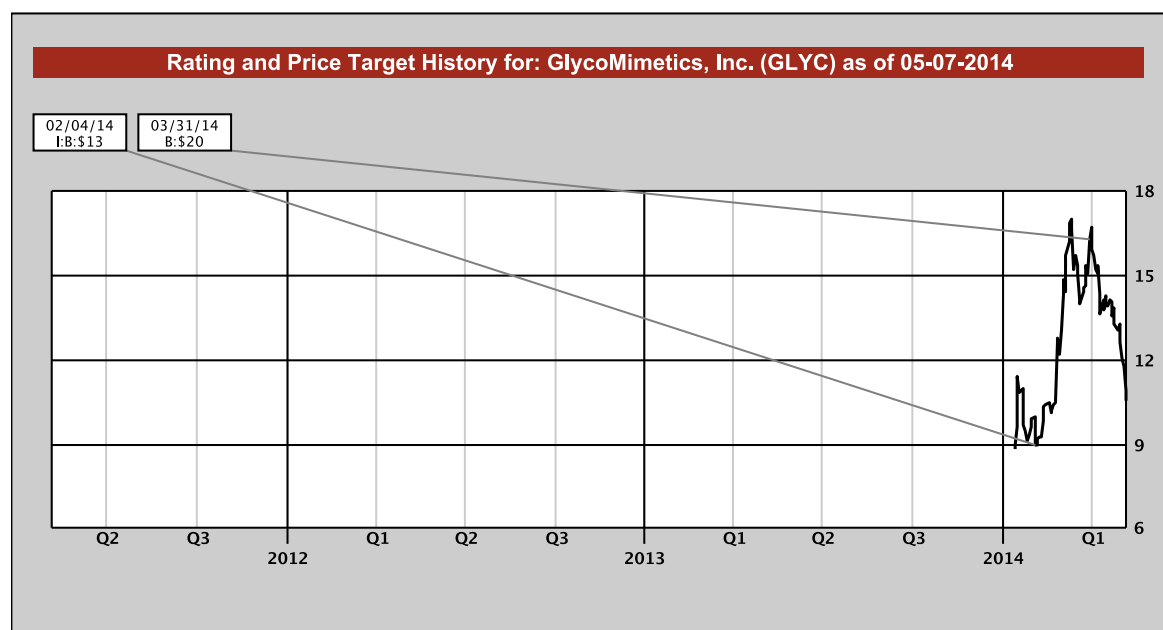
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