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GlycoMimetics

Biotechnology

US Equity Research
22 January 2015

BUY
unchanged

PRICE TARGET US$12.00
unchanged

Price (21-Jan)	US$7.09
Ticker	GLYC-NASDAQ

52-Week Range (US$):	6.02 - 18.99
Avg Daily Vol (M) :	94.3
Shares Out. (M) :	20.2
Market Cap (US$M):	143

FYE Dec	2013A	2014E	2015E
Revenue (US$M)	4.0	25.0	35.0
EPS Adj&Dil (US$)	(8.85)	(0.19)	(0.09)

Quarterly Revenue	Q1	Q2	Q3	Q4
2013A	3.8	0.1	0.1	0.1
2014E	0.0A	15.0A	0.0	10.0
2015E	35.0	0.0	0.0	0.0

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	0.04	(3.70)	(3.68)	(1.51)
2014E	(0.30)A	0.39A	(0.41)	0.07
2015E	1.51	(0.45)	(0.48)	(0.49)

Source: FactSet

GlycoMimetics is a clinical-stage biotech company focused on novel glycomimetic (carbohydrate imitating) drugs.

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Company Update

Manufacturing issues solvable; expect initiation of Phase 3 trial in 2015

Expect manufacturing issues to resolve from Pfizer and Phase 3 trial to start in 2015, major catalyst

After speaking with experts in the drug chemical specialty, we believe Pfizer's manufacturing issues with Rivipansel, GLYC's selectin inhibitor for the treatment of vaso-occlusive crisis (VOC), are solvable and expect initiation of Phase 3 trials to begin some time in 2015. GLYC company guidance states the manufacturing problem is with the buffering solution, which we believe is manageable. Based on our research, the compound needs to find the correct buffer to match the ionic concentration of all selectins, including L- and P-selectin, which require negatively charged sulfates, and E-selectin, which does not. We find this issue manageable as we feel Pfizer has the resources to appropriately conduct batch testings of various buffers that fit with the drug. Importantly, there are no changes to the active pharmaceutical ingredient and no concerns over stability. This is a significant positive since it is extremely difficult to amend stability of the drug without affecting the drug's vehicle, excipients, and, importantly, original chemical structure. From the experts' standpoint, the manufacturing issue can be resolved. We continue to await further updates from Pfizer, although we believe the issue will be resolved, removing the overhang from the stock.

Phase 3 trial design optimized vs. prior Phase 2 trial; higher confidence for success

We believe the Phase 3 trial is positioned for success based on the positive results seen with the prior Phase 2 study. Although the Phase 2 data did not hit statistical significance due to the low sample size (n = 76), there was a trend toward observed benefit in efficacy where the median and mean time to discharge reduced by 84 (p=0.092) and 55 hours (p=0.096), respectively, which we find to be clinically meaningful to hospital physicians. The Phase 3 trial will address the sample size limitation by enrolling ~350 patients suffering from VOC, which we believe will increase the chance of achieving a statistical benefit in the endpoint of readiness for discharge.

GMI-1271 may be interesting surprise as second asset

GMI-1271, an E-selectin inhibitor to AML cells, showed favorable preclinical results at ASH 2014 when used in combination with first-line AML therapies. We believe that treatment with GMI-1271 may result in lower bone marrow toxicity due to its inhibition of E-selectin, thereby making hematopoietic stem cells divide less frequently and protecting them from chemotherapy agents that target rapidly dividing cells. The company plans on conducting a Phase 1/2 trial in as an adjunct to standard chemotherapy in AML patients by 1Q15, with possible data readout YE15. Although we currently do not include GMI-1271 in our valuation, we believe positive data could move the stock substantially higher, given the fact that the compound is wholly owned by GLYC.

Formulation problem not surprising based on chemical structure of selectins; we view it as manageable

Rivipansel (GMI-1070) is a synthetic molecule designed to inhibit all three selectin types (a pan-selectin inhibitor). Selectins are glycoprotein cell adhesion molecules implicated in inflammatory processes which can worsen vaso-occlusive crisis for sickle cell disease. To achieve adequate therapeutic activity in certain inflammatory disorders, inhibition of all three selectin types (E-selectin, L-selectin and P-selectin) may be required, which is the primary mechanism of action for Rivipansel.

All three selectins bind to a common carbohydrate domain shared by silyl $Le^{a/x}$. However, to functionally bind to sialyl $Le^{a/x}$, both P- and L-selectins require an additional interaction with negatively charged sulphate group, while E-selectin has no such requirement and can bind to $Le^{a/x}$ in glycolipids easily (Ernst B et al. *Nature Reviews*. 2009). Because of the difference in ion charges, specifically the involvement of negatively charged groups in the binding of L- and P-selectin, we believe that the formulation issue with Rivipansel is not surprising as it is difficult to design a buffer system to accommodate both the charged P- and L- selectin molecules and the uncharged E-selectin molecule.

We believe this is the main cause of the formulation issue that Pfizer is currently facing, but believe the problem will be resolved soon. Pfizer has the resources to diligently batch test a plethora of buffering agents to patch Rivipansel. After speaking with experts in the field about this situation, we are further confident in the fact that the manufacturing problem will be resolved soon and allow the drug to enter pivotal Phase 3 studies, a significant catalyst to the stock.

Figure 1: GLYC income statement

	2011A	2012A	2013A	Q1/14A	Q2/14A	Q3/14E	Q4/14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E
GMI-1070																		
US	-	-	-	-	-	-	-	-	-	-	-	16.4	44.3	48.0	54.9	62.6	67.4	72.6
Ex-US													22.8	37.5	62.8	69.7	77.2	80.7
Product revenues	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**16.4**	**67.1**	**85.6**	**117.7**	**132.4**	**144.6**	**153.3**
Collaboration revenue	3.8	15.3	4.0	-	15.0		10.00	25.0	35.0	35.0	60.0	50.0		50.0		-	-	-
Total revenues	**3.8**	**15.3**	**4.0**	**-**	**15.0**	**-**	**10.0**	**25.0**	**35.0**	**35.0**	**60.0**	**66.4**	**67.1**	**135.6**	**117.7**	**132.4**	**144.6**	**153.3**
Cost of goods sold		-	-	-	-	-	-											
Gross Profit	**3.8**	**15.3**	**4.0**	**-**	**15.0**	**-**	**10.00**	**25.0**	**35.0**	**35.0**	**60.0**	**66.4**	**67.1**	**135.6**	**117.7**	**132.4**	**144.6**	**153.3**
R&D expense	7.8	9.4	11.7	3.9	5.4	6.0	7.0	22.2	29.1	60.0	60.6	61.2	61.8	62.4	63.1	63.7	64.3	65.0
SG&A expense	2.1	2.2	2.9	1.2	1.6	1.7	1.8	6.3	7.5	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9	5.2
Other operating expense	-	0.0	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total operating expense	**9.9**	**11.6**	**14.6**	**5.1**	**7.0**	**7.7**	**8.8**	**28.5**	**36.6**	**63.5**	**64.3**	**65.1**	**65.9**	**66.7**	**67.5**	**68.4**	**69.3**	**70.1**
Operating income	**(6.1)**	**3.6**	**(10.6)**	**(5.1)**	**8.1**	**(7.7)**	**1.2**	**(3.5)**	**(1.6)**	**(28.5)**	**(4.3)**	**1.4**	**1.2**	**68.9**	**50.2**	**64.0**	**75.4**	**83.2**
Net Interest/Investment income	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					0.1	0.1	0.1	0.1	0.1
Other non-operating income (expense)	-	(0.0)	(0.0)	0.0				-	-	-	-	-	-	-	-	-	-	-
Interest and other, Net	0.0	(0.0)	(0.0)	-	-	-	-	-	-	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.2)	(0.3)
Pre-tax income	**(6.1)**	**3.6**	**(10.6)**	**(5.1)**	**8.1**	**(7.7)**	**1.2**	**(3.5)**	**(1.6)**	**(28.5)**	**(4.3)**	**1.4**	**1.2**	**68.9**	**50.3**	**64.0**	**75.4**	**83.2**
Net income (loss)	**(6.1)**	**3.6**	**(10.6)**	**(5.1)**	**8.0**	**(7.7)**	**1.2**	**(3.5)**	**(1.6)**	**(28.5)**	**(4.3)**	**1.4**	**1.2**	**68.9**	**50.3**	**64.0**	**75.4**	**83.2**
Basic EPS	**(6.58)**	**3.93**	**(8.85)**	**(0.30)**	**0.42**	**(0.41)**	**0.07**	**(0.19)**	**(0.09)**	**(1.53)**	**(0.23)**	**0.07**	**0.06**	**3.64**	**2.64**	**3.35**	**3.92**	**4.30**
Diluted EPS	**(6.58)**	**0.33**	**(8.85)**	**(0.30)**	**0.39**	**(0.41)**	**0.07**	**(0.19)**	**(0.09)**	**(1.53)**	**(0.23)**	**0.07**	**0.06**	**3.64**	**2.64**	**3.35**	**3.92**	**4.30**
Basic shares outstanding	0.9	0.9	1.2	17.2	18.8	18.9	19.0	18.5	18.5	18.6	18.7	18.8	18.9	19.0	19.0	19.1	19.2	19.3
Diluted shares outstanding	0.9	11.0	1.2	17.2	20.2	18.9	19.0	18.5	18.5	18.6	18.7	18.8	18.9	19.0	19.0	19.1	19.2	19.3

Source: Company reports, Canaccord Genuity estimates

Figure 2: GLYC valuation

Product	Peak Sales ($MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value ($MM)	Value / Share
GMI-1070								
US	$854	2024	$344	1/1/2018	3.0	40%	$103	$5
Ex-US	$949	2024	$488	1/1/2019	4.0	40%	$132	$7
Total Product Value							**$235**	**$12**
Total Equity Value							**$235**	**$12**
Shares Outstanding (MM)							19	

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	4%
Discount Rate	10%

Source: Canaccord Genuity Estimates

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Target Price / Valuation Methodology:

GlycoMimetics - GLYC

Our price target of $12 is based on a probability adjusted NPV analysis.

Risks to achieving Target Price / Valuation:

GlycoMimetics - GLYC

Clinical risk -- GlycoMimetics' current Phase 3 trial may not be successful. We note that there has been relatively little drug development in SCD and no successful clinical trials that have led to the approval of drugs for the disease based on the endpoint GlycoMimetics is pursuing. Further, the Phase 2 trial of Rivipansel did not meet its primary endpoint (the same endpoint in the Phase 3 trial design) due to data variability. However, we feel the expansion of the patient numbers in the upcoming Phase 3 trial will compensate for the data variability inherent to SCD trials. Additionally, the current manufacturing issues from Pfizer may significantly delay the start of Phase 3 trials and push back our expected launch date of 2018 even further. Clinical risk -- Additional clinical investigation may show Rivipansel to have an unacceptable safety and tolerability signal. GMI-1070's selectin-based mechanism could potentially interfere with immune responses to infection, thereby increasing risk of infections, opportunistic and otherwise. The only serious adverse event in the Phase 2 trial was one case that was controlled and resolved without discontinuation of treatment. Regulatory risk -- Rivipansel may not be approved by the FDA and/or EMA despite Phase 3 success. We note the only approved drug for treatment of SCD is indicated for the prevention of the number of crises, rather than reduction of the duration of crisis (the trial design). There is no precedent for the approval of SCD drugs based on reduction of length of hospitalization. Competitive risk -- GlycoMimetics faces potential competition from other agents seeking to decrease the time to resolution of SCD crises, as well as indirect competition from agents being developed to prevent the onset of crises. Commercialization risk -- There is little to no precedent for the successful promotion to the sickle cell disease market. Hydroxyurea, the only currently-approved drug for the treatment of SCD, has been available in multiple generic forms for SCD for a number of years, and is no longer promoted by Bristol-Myers, its original SCD sponsor. Commercial uptake has historically been extremely limited. As such, we see no precedent for the successful launch and promotion of a drug for SCD. Reimbursement risk -- There is no guarantee that GlycoMimetics, or its partners, will garner reimbursement for GMI-1070. There has historically been significant skepticism regarding the market opportunity in SCD due to concerns about insurance coverage rates of the affected population. We also note GMI-1070's initially pursued indication would dictate its use in the hospital setting, which will require prior approval from hospital P&T committees. Financing risk -- GlycoMimetics will likely require additional funding, which may be sought in the equity markets. An equity raise could impact the price of GLYC's stock price, especially if investors believe they will experience meaningful dilution.

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	#	%	%
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Hold	348	32.22%	13.79%
Sell	51	4.72%	1.96%
Speculative Buy	48	4.44%	60.42%
	1080*	100.0%	

*Total includes stocks that are Under Review

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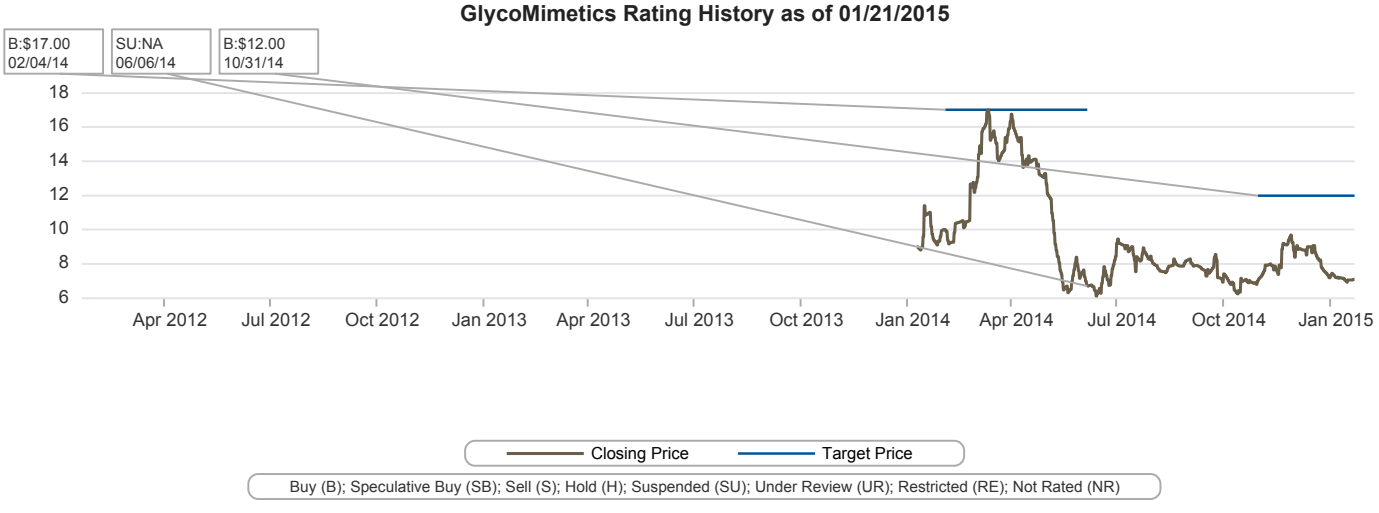

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