

# Equity Research

August 6, 2014

**Price: \$14.77** (08/5/2014) **Price Target: \$40.00** 

#### **OUTPERFORM (1)**

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#### **Key Data**

Symbol NASDAQ: GNCA 52-Week Range: \$23.99 - 10.90 Market Cap (MM): \$255.9 Net Debt (MM): \$(49.3) Cash/Share: \$38.97 Dil. Shares Out (MM): 17.3 Enterprise Value (MM): \$328.2 NA ROE (LTM): NA BV/Share: \$(248.44) Dividend: NA

FY (Dec)	2013A	2014E	2015E	
Revenue (MM	I)			
Year	\$1.0	\$0.0	\$0.0	
EV/S	328.2x	-		
Earnings Per S	Share			
Q1	-	\$(0.76)A	_	
Prior Q1	-	-	-	
Q2	-	\$(0.41)A	-	
Prior Q2	-	\$(0.46)	-	
Q3	-	\$(0.55)	-	
Prior Q3	-	\$(0.53)	-	
Q4	-	\$(0.54)	-	
Prior Q4	-	\$(0.52)	-	
Year	\$(2.12)	\$(2.10)	\$(2.05)	
P/E	NM	NM	NM	

# Genocea Biosciences

# **Earnings Update**

# Reports Q2:14, GEN-003 and -004 Moving Forward

# The Cowen Insight

GNCA reported Q2 financials and updated its clinical progress. GNCA ended Q2 with \$59.2MM in cash, sufficient for operations through YE:15. A Ph. II challenge trial of GEN-004 will begin this quarter, with data expected in mid-2015. GEN-003's Ph. II dose optimization trial will also report initial data in mid-2015. We believe GNCA is undervalued on GEN-003's potential, and remain at Outperform.

#### **Genocea Funded Through 2015**

Genocea reported a Q2:14 net loss of \$7.1MM, or \$0.41 per share and ended Q2 with a cash balance of \$59.2MM. Management projects this will be sufficient to fund operations through the end of 2015.

## **GEN-004 Challenge Trial To Begin This Quarter**

Animal models have shown that  $T_H17$  cells are capable of directing a sterilizing immune response to pneumococcal infections. GEN-004 is a candidate universal pneumococcal vaccine designed to elicit  $T_H17$  cells. During Q2, GNCA announced that a Phase I trial in healthy volunteers demonstrated that GEN-004 successfully elicited  $T_H17$  cells and generated no serious adverse events. This data will be presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) meeting in Washington, DC on Sept. 5-9. Genocea plans to initiate a 90 subject Phase II challenge study during Q3:14. Following vaccination, subjects will be nasally challenged with pneumococcal strain 6B. Nasal washes will then be obtained in order to assess 1) the ability of the pneumococcus to colonize the nasal passages and 2) the frequency of TH17 responses at the mucosal surface. Management expects to report data from this trial in mid-2015.

#### **GEN-003 Dose Ranging Phase II Underway**

GEN-003 is a candidate HSV-2 therapeutic vaccine. Our consultants believe a Phase I/ II trial demonstrated approvable efficacy at 6-months (65% reduction in genital lesions and 40% reduction in viral shedding). At 12-months, lesion rates remained reduced by 42%, though viral shedding had returned to baseline. Importantly, GEN-003 maintained a clean safety profile throughout the study. Full data is to be presented at IDWeek 2014 in Philadelphia, Oct. 8-12. While GEN-003 has already demonstrated a potentially approvable profile, management and our consultants think dose and/or treatment regimens can be further optimized to possibly improve peak efficacy and/or durability. Genocea has already begun enrolling a Phase II dose optimization study. This trial will test combinations of antigen (30mg and 60mg) and adjuvant (25mg, 50mg, and 75mg). Each dosage combination will be given to 30 patients. Shedding and lesion data from the initial 3 months post-vaccination are expected to be reported in mid-2015.

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#### **Our Investment Thesis**

Genocea Biosciences is a clinical stage company developing sophisticated, high value vaccines and in particular is a leader in the discovery and development of T-cell vaccines. Genocea has four visible programs, including two in clinical development. GEN-003 is a therapeutic vaccine for HSV-2, the cause of genital herpes. GEN-003 has produced strong proof-of-concept Phase II data that our consultants have called "impressive". We estimate a safe and effective HSV-2 therapeutic vaccine would have \$1B+ sales potential. Genocea has also advanced a pneumococcal vaccine into early clinical development. Our analysis suggests that Genocea is undervalued just on GEN-003's potential in HSV-2, with no other contribution from Genocea's other programs or value attributed to the ATLAS platform. We expect Genocea to outperform the market over the next 12 – 24 months as GEN-003 and GEN-004 progress through development.

# **Forthcoming Catalysts**

- Present data from GEN-004's Phase I trial at ICAAC (Sep 2014)
- Present final data from GEN-003's Phase I/IIa trial at IDWeek 2014 (Oct 2014)
- Data from GEN-003's Phase II dose titration trial (mid-2015)
- Data from GEN-004's Phase II challenge trial (mid-2015)

# **Base Case Assumptions**

- GEN-003 is successfully developed and generates \$750MM in revenue by 2025
- GEN-004 progresses through development but does not generate substantial revenue before 2020
- Genocea's other vaccine candidates do not create significant shareholder value before 2020

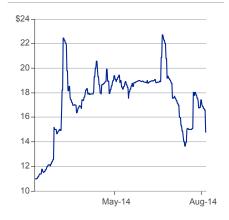
# **Upside Scenario**

- GEN-003 is successfully developed and generates more than \$750MM in revenue by 2025
- GEN-004 progresses through development and drives significant shareholder value
- Genocea's other vaccine candidates look promising and are attributed much value

# **Downside Scenario**

- GEN-003 is not successfully developed and/or generates less than \$750MM in revenue by 2025
- GEN-004 does not progress
- Genocea's other vaccine candidates do not create significant shareholder value before 2020
- Genocea's ATLAS technology fails to generate new candidates or partnerships

#### **Price Performance**



Source: Bloomberg

# **Company Description**

Genocea's key advantages in the competitive field of vaccine discovery and development are novel and proprietary technologies to identify and validate vaccine antigens that generate a strong cellular (T Cell derived) immune response against pathogens that are resistant to conventional antibody-eliciting vaccines. Genocea has optimized its ATLAS platform in order to screen more exhaustively than others for epitopes that initiate CD4 (helper T Cells) and CD8 (cytotoxic T Cells). Genocea has four visible programs, including two in clinical development. GEN-003 is a therapeutic vaccine for HSV-2, the cause of genital herpes. GEN-004 is a pneumococcal vaccine in early clinical development. Genocea has research programs in Chlamydial vaccines and malarial vaccines.

#### **Analyst Top Picks**

	Ticker	Price (08/5/2014)	Price Target	Rating
Gilead Sciences	GILD	\$92.27	\$95.00	Outperform
BioMarin Pharmaceutical	BMRN	\$64.96	\$95.00	Outperform
Portola Pharmaceuticals	PTLA	\$25.56	\$45.00	Outperform

#### Cowen and Company

**Equity Research** 

#### Genocea Biosciences

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#### Investment Thesis

Genocea Biosciences is a clinical stage company developing sophisticated, high value vaccines, and in particular is a leader in the discovery and development of T cell vaccines. Genocea's key advantages in this complex area of drug development are novel and proprietary technologies to identify and validate vaccine antigens that generate a strong cellular (T cell derived) immune responses against pathogens that are resistant to conventional antibody-eliciting vaccines. The company and its founders have a nearly 20-year history of identifying T cell antigens in novel ways. This experience has allowed Genocea to optimize its ATLAS platform in order to screen more rapidly and exhaustively than others for epitopes that initiate CD4 (helper T cells) and/or CD8 (cytotoxic T cells) T cell responses. ATLAS is a high throughput approach to antigen identification that allows T cells from many different patients to be screened and compared to identify not only antigens, but protective antigens. ATLAS also allows Genocea to exploit new advances in immunology - such as rapidly screening for T<sub>H</sub>17 antigens quickly after it was discovered that these newly characterized T cells were a key part of a protective response against pneumococcal disease. Genocea has four visible programs, including two in clinical development. GEN-003 is a therapeutic vaccine for HSV-2, the cause of genital herpes. GEN-003 has produced strong proof-of-concept Phase II data that our consultants have called "impressive." We estimate a safe and effective HSV-2 therapeutic vaccine would have \$1B+ sales potential. Genocea has also advanced a pneumococcal vaccine into early clinical development. In addition, the company has research programs in chlamydial and malarial vaccines. We expect the company to keep collaborating with academic and foundation scientists who wish to apply Genocea's powerful ATLAS technology to new problems in vaccine development. Our analysis suggests that Genocea is undervalued just on GEN-003's potential in HSV-2, with no other contribution from Genocea's other programs or value attributed to the ATLAS platform. We expect Genocea to outperform the market over the next 12-24 months as GEN-003 and GEN-004 progress through development.

# Genocea Biosciences

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# Genocea - Upcoming Milestones/Events

Indication/Milestone	Timing
Initiation of GEN-004's Phase II challenge trial	Q3:14
Present data from GEN-004's Phase I trial in healthy volunteers at ICAAC	Sep 2014
Present final data from GEN-003's Ph. I/IIa trial in HSV-2 patients at IDWeek 2014	Oct 2014
Initial data from post dose 3 analysis in GEN-003's Phase II dose titration trial	Mid:15
Data from GEN-004's Phase II challenge trial	Mid:15
Initiation of GEN-003's Phase II dose regimen trial	H2:15

Source: Cowen and Company

# Genocea Quarterly P&L

	2	013A	Q1:14A	. (	Q2:14A	Q3:14E	Q4	i:14E	2014E
GEN-003			-		-	-		-	_
GEN-004			-		-	-		-	-
Contract, Grant Revenue And Other		1.0							
Total Revenue		1.0	-		-	-		-	-
COGS Gross Margin			-		-	-		-	-
R&D		14.5	4.4	Ì	4.6	7.0		7.0	23.0
SG&A		4.5	2.0	)	2.4	2.5		2.5	9.3
Other									
Operating Expenses		19.0	6.4	į.	6.9	9.5		9.5	32.3
Operating Income / (Loss)		(18.0)	(6.4	<b>i</b> )	(6.9)	(9.5)	)	(9.5)	(32.3)
Interest Income, net		(0.7)	-		(0.2)	(0.2)	)	(0.2)	(0.6)
Other Income		(0.2)	(1.0	))					
Pretax net income		(18.9)	(7.3	3)	(7.1)	(9.7)	)	(9.7)	(32.9)
Accretion of redeemable convertible preferred stock Taxes		(1.2)	(0.2	2)	-	-		-	-
Tax Rate			09	6	0%	0%		0%	0%
GAAP Net Income		(20.1)	(7.5	5)	(7.1)	(9.7)	)	(9.7)	(32.9)
GAAP EPS	\$	(2.12)	\$ (0.76	3) \$	(0.41)	\$ (0.55)	\$	(0.54)	(2.10)
Diluted Shares Outstanding (MM)		9.5	9.9	)	17.3	17.5		17.9	15.7

Source: Cowen and Company

# Genocea Annual P&L

	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E
GEN-003	-	-	-	-	-	-	-	15.0
GEN-004	_	-	-	-	-	-	-	-
Contract, Grant Revenue And Other	1.0	-	-	-	-	-	-	-
Total Revenue	1.0	-	-	-	-	-	-	15.0
COGS	-	-	-	-	-	-	-	1.5
Gross Margin		0%	0%	0%	0%	0%	0%	90%
R&D	14.5	23.0	27.5	30.0	45.0	55.0	65.0	75.0
SG&A	4.5	9.3	11.0	12.0	15.0	25.0	50.0	115.0
Other	-	-	-	-	-	-	-	-
Operating Expenses	19.0	32.3	38.5	42.0	60.0	80.0	115.0	191.5
Operating Income / (Loss)	(18.0)	(32.3)	(38.5)	(42.0)	(60.0)	(80.0)	(115.0)	(176.5)
Interest Income, net	(0.7)	(0.6)	(1.0)	(1.0)	-	2.0	6.0	8.0
Other Income								
Pretax net income	(18.9)	(32.9)	(39.5)	(43.0)	(60.0)	(78.0)	(109.0)	(168.5)
Accretion of redeemable convertible preferred stock								
Taxes	_	-	-	-	-	-	-	-
Tax Rate	-	0%	0%	0%	0%	0%	0%	0%
GAAP Net Income	(20.1)	(32.9)	(39.5)	(43.0)	(60.0)	(78.0)	(109.0)	(168.5)
GAAP EPS	(2.12)	(2.10)	(2.05)	(1.70)	(2.35)	(3.00)	(3.10)	(4.10)
Diluted Shares Outstanding (MM)	9.5	15.7	19.3	25.3	25.5	26.0	35.2	41.1

Source: Cowen and Company

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# Valuation Methodology And Risks

# **Valuation Methodology**

#### **Biotechnology:**

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

#### **Investment Risks**

#### **Biotechnology:**

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

#### **Risks To The Price Target**

Much of Genocea's valuation rests on the value of its ATLAS vaccine discovery technology platform, and the revenue potential of its pipeline programs. Determining the value of a technology platform is difficult. Many factors could alter the value, including competition from newer technology platforms, the success or failure of Genocea's candidate vaccines, and the attractiveness of vaccine development more generally. Projecting future sales for any product is difficult, and this is particularly the case for candidates that have yet to be approved. Genocea's stock could be impacted by changes in the regulatory, commercial, or competitive environment for its candidate vaccines or for vaccines more generally. Moreover, the market exclusivity of Genocea's vaccines is largely dependent on their patents, which could be subject to challenge.



#### **Stocks Mentioned In Important Disclosures**

Ticker	Company Name
BMRN	BioMarin Pharmaceutical
GNCA	Genocea Biosciences
GILD	Gilead Sciences
PTLA	Portola Pharmaceuticals

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Genocea Biosciences and Portola Pharmaceuticals have been client(s) of Cowen and Company, LLC in the past 12 months.

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Cowen and Company Rating System effective May 25, 2013

Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

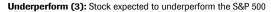
Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

#### Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

#### **Cowen And Company Rating Definitions**

#### Distribution of Ratings/Investment Banking Services (IB) as of 06/30/14

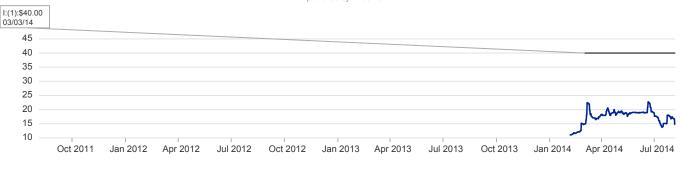
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	417	58.57%	94	22.54%
Hold (b)	279	39.19%	7	2.51%
Sell (c)	16	2.25%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.

#### Genocea Biosciences Rating History as of 08/05/2014







# BioMarin Pharmaceutical Rating History as of 08/05/2014

powered by: BlueMatrix

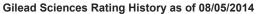




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#### Portola Pharmaceuticals Rating History as of 08/05/2014

Target Price

Closing Price





#### **Legend for Price Chart:**

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

#### Genocea Biosciences

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# **Analyst Profiles**



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Phil Nadeau is a senior analyst covering biotech. He has been at Cowen for 12 years. Phil holds an SB/M.Eng from MIT, and a Ph.D. from Harvard.



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Marc Frahm is an associate covering biotechnology. He joined Cowen in July 2013 after doing biomedical research at Duke University.

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