

# **Equity Research**

February 3, 2015

**Price:** \$8.58 (01/30/2015) **Price Target:** \$40.00

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

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#### **Key Data**

Symbol NASDAQ: GNCA Market Cap (MM) \$151.1

# Genocea Biosciences

Quick Take: Company Update

# Highlights From Meetings With Management

# The Cowen Insight

Yesterday we hosted investor meetings for GNCA senior management. The next several months will be eventful, with top-line data from GEN-003's dose optimization study expected in June, and GEN-004's challenge study interim results coming in mid-2015. We continue to believe that GNCA is undervalued on GEN-003's potential alone, and remain at Outperform.

#### Two Meaningful Pipeline Events On Track For Mid-2015.

Yesterday we hosted investor meetings in New York for Genocea's CEO Chip Clark, CMO Seth Hetherington, and CFO Jonathan Poole. With data from both GEN-003 and GEN-004 on track for mid-year, 2015 is shaping up to be both important and formative for Genocea. Highlights from the meetings follow:

# Top-Line Results From GEN-003's Dose Optimization Trial Expected In June.

Genocea initiated a Phase II dose optimization trial in July 2014 and it has completed enrollment of 310 subjects. This trial will test combinations of antigen (30mg and 60mg) and adjuvant (25mg, 50mg, and 75mg), and compare each to placebo. In total there will be 7 dose groups, with about 45 subjects per group. Post-dose shedding and lesion data will be released in June 2015. One of the 7 cohorts is testing the same adjuvant (50mcg) and protein (30 mcg) doses tested in the prior Phase I/IIa. Therefore, management is hopeful that the results of the dose optimization trial will confirm GEN-003's impact on shedding and lesion rates seen in the Phase I/IIa. In that study the 30mcg protein and 50mcg adjuvant dose produced a 48% reduction in genital leasion rate, and a 52% reduction in viral shedding rate, after dose 3. As our consultants were impressed by the Phase I/IIa data, we would consider a replication of the results a good outcome, and a key de-risking event for Genocea. Should Genocea find a dose with improved efficacy, that would be a better-case scenario which could make GEN-003's profile even more compelling.

Phase II Dose Regimen Trial To Start Toward The End Of 2015, Produce Data In Mid-2016. After the completion of the dose optimization trial, Genocea expects to begin a second Phase II trial testing various dosing regimens. The "Dose Regimen" trial will employ the best dose from the dose optimization trial, and will compare the effects of the number of doses adminstered (eg 3 monthly injections vs 2 monthly injections) on efficacy. Genocea is hopeful that this trial will finalize the product profile for Phase III. Management expects to have an end of Phase II meeting with the FDA in 2016, with the initiation of pivotal trials after.

# Interim Results From GEN-004's Phase IIa Challenge Study Expected

**Mid-2015.** Genocea began a randomized Phase II human challenge study during Q3:14. Approximately 90 healthy adults will be enrolled to receive either 3 doses of GEN-004 or placebo. 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

Please see addendum of this report for important disclosures.

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of  $T_H17$  responses at the mucosal surface. Interim results are on track for mid-2015. Following the challenge study, Genocea will begin a Phase II toddler study to identify the pediatric dose. The trial will begin in 2016 and assess safety along with the impact of GEN-004 on colonization and disease (such as otitis media).

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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.

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# **Stocks Mentioned In Important Disclosures**

Ticker	Company Name
GNCA	Genocea Biosciences

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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

**Underperform (3):** Stock expected to underperform the S&P 500

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

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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 12/31/14

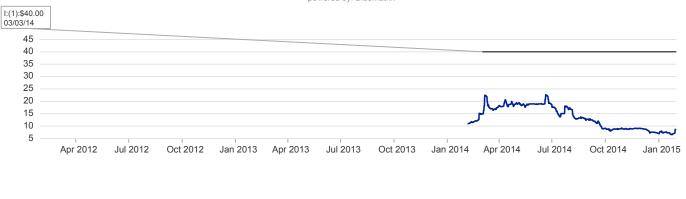
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.50%	109	23.64%
Hold (b)	288	37.80%	14	4.86%
Sell (c)	13	1.71%	0	0.00%

(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. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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# Genocea Biosciences Rating History as of 01/30/2015





# **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

Target Price

Closing Price

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