Nov 13, 2024

Healthcare

OCGN

NASDAQ

Rating

Outperform

Unchanged

Current Price

$1.02

Target Price

$8.00

Market Capitalization

293.6M

Shares Outstanding

287.9M

Float

277.8M

Institutional Holdings

25%

12-Month Low/High

$0.35/$2.11

Average 90-Day Volume

3560000

Fiscal Year End

12/31/2024

Revenues ($ MIL)

Period	2023A	2024E	2024E
Q1	0.0	1.0A	0.0E
Q2	0.0	1.1A	0.0E
Q3	0.0	1.2A	0.0E
Q4	0.0	1.2E	0.0E
	0.0	4.6E	0.0E

EPS ($)

Period	2023A	2024E	2025E
Q1	(0.07	(0.05)A	(0.07)E
Q2	(0.10)	(0.054A	(0.08)E
Q3	(0.06)	(0.05)E	(0.08)E
Q4	(0.07)	(0.06)E	(0.09)E
	(0.29)	(0.22)E	(0.32)E

Ocugen

Ocugen Clinical Showcase Highlights Fundamentals, Clinical Data, and Patient Stories

Ocugen Held A Meeting With Scientists, Doctors, and Patients. On November 12, Ocugen held a Clinical Showcase meeting to present the scientific basis of its Gene Modifier technology, interim data updates from its clinical trials, and allow patients to discuss their experiences with the treatments.

First OCU410 Data Shows Efficacy. The Phase 2 ArMaDa trial is testing OCU410 in Geographic Atrophy (GA), a lesion in patients with dry age-related macular degeneration that leads to blindness. The presentations included its four mechanisms of action and the clinical outcomes from the initial patient cohorts in the dose-escalation stage of the trial. These data at 6 months compare favorably to approved complement inhibitors for GA.

OCU410ST Has Completed The Phase 1 Trial. OCU410ST is in development for Stargardt disease, an rare genetic disease that leads to macular degeneration and loss of vision. Data from the completed Phase 1 trial was presented showing safety and tolerability. At six months after treatment, patients had slower lesion growth, preservation of the retinal structure, and improvement or stabilization of visual function (best corrected visual acuity, BVCA).

A Panel of Patients Told About Their Treatments. One of the most striking parts of the presentation was the panel with patients that have been treated with one of the Ocugen products. They told about their diagnosis, course of disease, and described the treatment. All were happy with the outcomes and would recommend treatment to others. One added that he was looking forward to having his control eye treated.

Conclusion. Ocugen has made significant progress in all three of its clinical trials. OCU400 remains on schedule for a 1H2026 BLA, while the initial data from the OCU410 trial show that the drug is safe, effective, and could be superior to the complement inhibitor treatments that have recently been introduced. OCU410 could also have significant clinical benefit for an Orphan population. We are reiterating our Outperform rating and $8 price target.

Equity Research

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Refer to the last two pages for Analyst Certification & Disclosures

Ocugen (OCGN) | Current Price: $1.02 | Outperform | Nov 13, 2024

Summary. On November 12, Ocugen held a Clinical Showcase to present the scientific basis of its Gene Modifier technology, interim data updates from its clinical trials, and allow patients to discuss their experiences with the treatments.

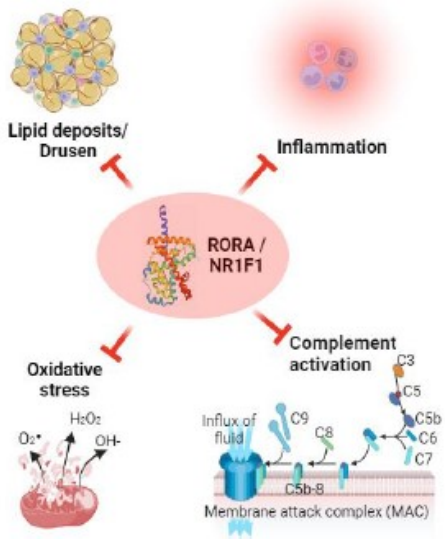
A Panel of Patients Told About Their Treatments. One of the most striking parts of the presentation was the panel with patients that have been treated with one of the Ocugen products. They told about their diagnosis and course of disease and described the treatment.

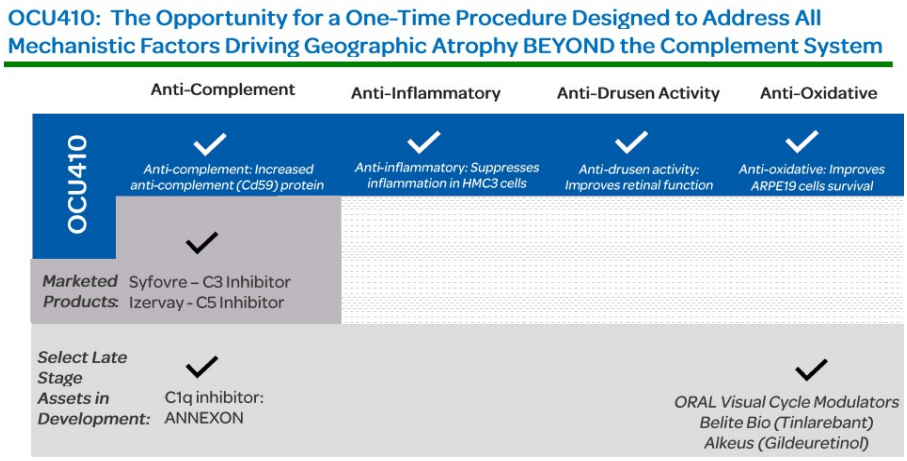
When answering questions from the audience, we also asked about the treatment, recovery time, and pain from the procedure. The patients said it was an outpatient treatment only taking about 90 minutes. Pain was minimal and recovery time was brief. All were happy with the outcomes and would recommend treatment to others. An RP patient who has recovered some of his lost vision commented that he was looking forward to having his control eye treated.

We also asked the doctors if the treatment was something that most ophthalmologists could perform without additional training. They said that the treatment uses standard techniques that any board certified ophthalmologist would know. One also mentioned that the logistics and preparation of the treatment was easy for doctors and hospitals to adopt. He commented that treatments that require special handling or could be difficult to prepare are avoided by some hospitals, but the Ocugen products can be handled easily and would not have that problem.

First OCU410 Data Shows Efficacy. OCU410 is currently in the Phase 2 ArMaDa trial for Geographic Atrophy (GA), a lesion in patients with dry age-related macular degeneration that leads to blindness. The presentations included description of its four mechanisms of action and the clinical outcomes from the initial patient cohorts in the dose-escalation stage of the trial. Although a small number of patients, these data show disease stabilization in all three patients evaluable. At 6 months, the patients showed a 21.6% decrease in lesion growth compared to the patient's untreated eye. This compares favorably approved complement inhibitors for GA like Syfovre (pegcetacoplan, Apellis) and Izervay (avacincaptad pegol, Astellas) with reductions of 12% or 14% depending on dosing.

Exhibit 1. OCU410 Has Four Mechanisms Of Action. As illustrated in the left panel, the RORA gene impacts lipid deposits (drusen), inflammation, complement activation and oxidative stress. Comparisons with mechanisms of other drugs for GA is shown in the chart.





Source: Ocugen, Inc.

OCU410ST Has Completed Phase 1. OCU410ST is in development for Stargardt disease, an rare genetic disease that leads to macular degeneration and loss of vision. Data from the completed Phase 1 trial was presented showing safety and tolerability. Six months after treatment, patients had 84% slower lesion growth than their untreated fellow eye. Four out of five patients (80%) showed preservation of the macular volume (retinal structure), and three out of five (60%) showed improvement or stabilization of visual function (best corrected visual acuity, BVCA).

Exhibit 2. OCU410ST Data From Low and Medium Doses Stabilized Or Improved Retinal Function.

Parameters for Assessment	Low 1	Low 2	Low 3	Med 2	Med 3	Overall Measures
Atrophic lesion growth (mm^2) compared to untreated eyes	●	N.D	●	●	N.D	
Visual Function Improvement (BCVA)	-	-	●	●	●	3/5 (60%)
Total Retinal Thickness (Change from BL)	●	●	-	●	-	3/5 (60%)
Macular Volume (Change from BL)	●	●	-	●	●	4/5 (80%)

● Parameters showing improvement or preservation in the treated eye

- Structural Improvement
  - Atrophic lesions grew slower by 84% in treated eyes when compared to untreated eyes
  - 4/5 (80%) of treated eyes demonstrated preservation of macular volume
  - 3/5 (60) of treated eyes demonstrated preservation of retinal thickness
- Visual Function (BCVA)
  - 3/5 (60%) treated eyes demonstrated stabilization or improvement in visual function

Source: Ocugen, Inc.

OCU400 Continues With Plans For Phase 3. The Modifier Gene technology delivers a single master control gene that regulates other genes in visual pathways. OCU400 is the most advanced product using the Modifier Gene technology, allowing it regulate downstream pathways with many genes. This "gene agnostic" approach is especially relevant in RP, an inherited disease in which the patient may have any combination of up to 100 mutations. Gene therapies that correct a single mutation would be ineffective or impractical for diseases like RP.

OCU400 is currently recruiting patients for its Phase 3 liMeliGhT (pronounced “Limelight”) study in retinitis pigmentosa (RP) and Leber congenital amaurosa (LCA). There are 15 sites in the US, and 5 to be added in Canada after approval from Health Canada. Enrollment is expected to be completed in 1H2025. The FDA has approved an expanded access program (EAP) that allows adults to be treated before approval. We believe this shows the FDA recognizes the impact of OCU400 and is confident in the safety to allow treatment outside of the clinical trial.

Data presented at the meeting demonstrates the benefits seen in early, middle, and advanced stages of RP and LCA. The BLA filing is on schedule for a filing with the FDA and MAA in 1H2026.

Conclusion. Ocugen has made significant progress in all three of its clinical trials. OCU400 remains on schedule for a 1H2026 BLA, while the initial data from the OCU410 trial show that the drug is safe, effective, and could be superior to the complement inhibitor treatments that have recently been introduced. OCU410 could also have significant clinical benefit for an Orphan population. We are reiterating our Outperform rating and $8 price target.

Company Profile

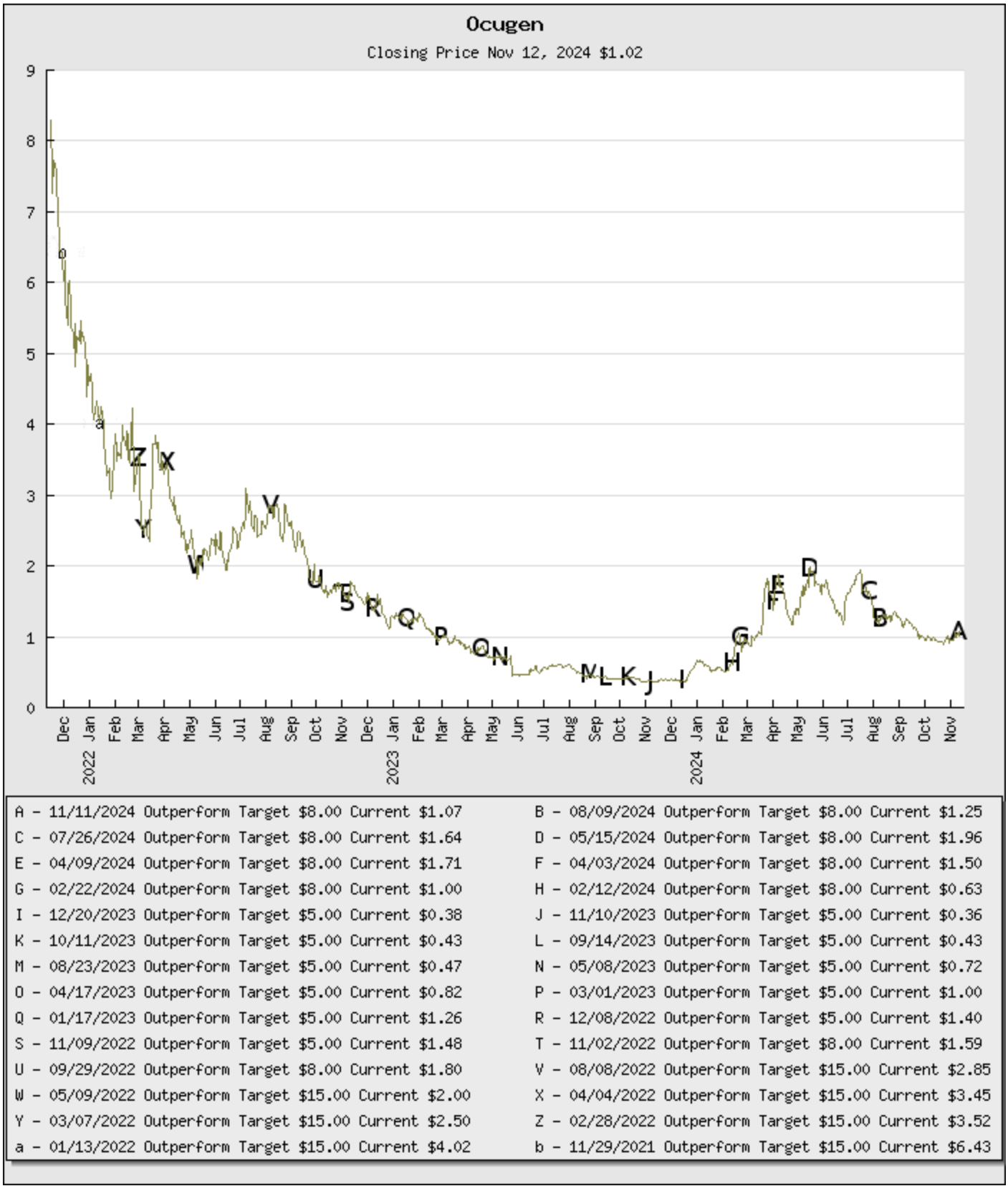
Ocugen, Inc. is a biotechnology company developing vaccines and gene therapy products. Its gene therapy technology is based on delivering genes that regulate and control the expression of other genes to affect pathways of disease and fusion proteins. Its nasal mucosal vaccines are in development for COVID-19 and influenza.

Fundamental Analysis

In our assessment, we give OCGN a score of 4.0 out of 5.0, which falls within the upper half of the "Above Average" range of 3.0 to 4.0 and warrants 4.0 checks. Our positive fundamental rating is based on the company's introduction of a COVID-19 vaccine and its gene therapy technology platform. We view the quality of management and the Board of Directors as above average due to extensive industry experience. For further explanation of our fundamental analysis, refer to the disclosures at the end of this report.

Valuation Summary

Our valuation is based on OCU400 continuing to make progress through clinical trials leading to approval in 2026. Our revenue models have been adjusted to include risk-adjusted revenues from OCU410 in its dAMD indication. We discount our estimated revenues by 50% to 75% allow for clinical development risk then estimate EPS, using the first full year of sales as the valuation year. We discount FY2027 EPS of $1.23 at 30% per year for a price target of $8 per share.



A - 11/11/2024 Outperform Target $8.00 Current $1.07	B - 08/09/2024 Outperform Target $8.00 Current $1.25
C - 07/26/2024 Outperform Target $8.00 Current $1.64	D - 05/15/2024 Outperform Target $8.00 Current $1.96
E - 04/09/2024 Outperform Target $8.00 Current $1.71	F - 04/03/2024 Outperform Target $8.00 Current $1.50
G - 02/22/2024 Outperform Target $8.00 Current $1.00	H - 02/12/2024 Outperform Target $8.00 Current $0.63
I - 12/20/2023 Outperform Target $5.00 Current $0.38	J - 11/10/2023 Outperform Target $5.00 Current $0.36
K - 10/11/2023 Outperform Target $5.00 Current $0.43	L - 09/14/2023 Outperform Target $5.00 Current $0.43
M - 08/23/2023 Outperform Target $5.00 Current $0.47	N - 05/08/2023 Outperform Target $5.00 Current $0.72
O - 04/17/2023 Outperform Target $5.00 Current $0.82	P - 03/01/2023 Outperform Target $5.00 Current $1.00
Q - 01/17/2023 Outperform Target $5.00 Current $1.26	R - 12/08/2022 Outperform Target $5.00 Current $1.40
S - 11/09/2022 Outperform Target $5.00 Current $1.48	T - 11/02/2022 Outperform Target $8.00 Current $1.59
U - 09/29/2022 Outperform Target $8.00 Current $1.80	V - 08/08/2022 Outperform Target $15.00 Current $2.85
W - 05/09/2022 Outperform Target $15.00 Current $2.00	X - 04/04/2022 Outperform Target $15.00 Current $3.45
Y - 03/07/2022 Outperform Target $15.00 Current $2.50	Z - 02/28/2022 Outperform Target $15.00 Current $3.52
a - 01/13/2022 Outperform Target $15.00 Current $4.02	b - 11/29/2021 Outperform Target $15.00 Current $6.43

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The fundamental assessment rating system is designed to provide insights on the company's fundamentals both on a macro level, which incorporates a company's market opportunity and competitive position, and on a micro/company specific level. The micro/company specific attributes include operating & financial leverage, and corporate governance/management. The number of check marks that a company receives is designed to provide a quick reference and easy determination of the company's fundamentals based upon the following five attributes of the company (weighting reflects the importance of each attribute in the overall scoring of company's fundamental analysis):

Attribute	Weighting
Corporate Governance/Management	20%
Market Opportunity Analysis	20%
Competitive Position	20%
Operating Leverage	20%
Financial Leverage	20%

For each attribute, the analysts score the company from a low of zero to a high of ten based upon the analysis described below. The final rating and resulting check marks is a result of dividing the overall score (out of 100%) by ten.

Rating	Score	Checks
Superior	9.1 to 10	Five Checks
Superior	8.1 to 9	Four & A Half Checks
Above Average	7.1 to 8	Four Checks
Above Average	6.1 to 7	Three & A Half Checks
Average	5.1 to 6	Three Checks
Average	4 to 5	Two & A Half Checks
Below Average	3 to 3.9	Two Checks
Below Average	2 to 2.9	One & A Half Checks
Low Quality	0 to 1.9	One Check

While these are the attributes currently used for the analyst's fundamental analysis, the attributes and weighting may be reviewed, updated with additional attributes, and/or changed in the future based on discussions with the analysts and recommendations from the Director of Research.

Following is the description of each attribute in the fundamental analysis.

Corporate Governance/Management

We believe that a review of corporate governance and assessment of the senior management are important tools to determine investment merit. Good corporate governance aligns management with the interests of stakeholders. As such, analysts are to rank the company on the basis of good corporate governance principles that may include rules and procedures, board composition and staggered term limits, rights and responsibilities, corporate objectives, monitoring of actions and policies, and accountability. In addition, analysts will assess issues with controlling shareholders and whether decisions have been made in the past that were in the interests of all shareholders. In addition, management will be assessed based on industry experience, expertise, and/or track record.

High ranking example: Board and management that is aligned with the interests of shareholders with incentives based on stock price appreciation and with an experienced management team known for exceptional shareholder returns.

Low ranking example: Concentrated ownership without independent directors that do not necessarily align with all shareholders' interests.

The Market Opportunity Analysis

In this review, the analyst assesses the company's macro environment as a measure of understanding the industry. Factors considered include the size and growth potential of the industry under various economic conditions, the emerging demands in the market, technological benefits/disruptions, competition, geographical opportunities, and customer demands/needs, and an assessment of supply and distribution channels. In addition, the analyst will review legal and regulatory trends, as well as potential shifts in consumer or social behavior and natural environment changes.

High rank example: A company in an industry that is growing revenues well above GDP rates (which are on average 2% plus) and/or may have unmet or under-served needs in a rapidly growing market opportunity.

Low rank example: A mature industry that is in secular decline and likely to grow below GDP rates.

Competitive Position

The evaluation of the company's competitive position is another macro environment attribute designed to measure the relevance, market share, position and value proposition, and sustainable differentiations of the company and its products/services within its industry. Ease of entry into the industry and the ability of other well-funded players to potentially enter the market would be determined. As such, the assessment would consider the company's strengths and advantages of its products/services against weaknesses and limitations. This may include the company's current brand awareness, pricing and cost structure, current market strategies and geographic penetration that may affect demand for its products/services. In addition, the company's competitors would be evaluated.

High rank example: An analyst would consider the company's product to be superior to its competitors and that should allow the company to gain market share.

Low rank example: A company with a "me-too" product that does not have any significant technology advantages in an industry that has low barriers to entry.

Operating Leverage

Simplistically, operating leverage is determined by the operating income relative to changes in revenue. The analyst will calculate the impact on sensitivity on gross margins and variable costs to determine operating leverage. The analyst will take into account the ability of the company to cut fixed and variable costs in a challenged revenue environment and technological changes that may impact operating expenses. In addition, the analyst is to assess corporate strategies that include capital investment, which may be required for sustainable revenue growth, marketing expenses, and the company's ability to attract and retain talent and/or employees. The analyst should focus on the revenue opportunity and determine the price elasticity of demand for the company's products or services. In other words, the analyst is to rank the company based on improved operating margins going forward on an absolute and relative basis.

High rank example: A company that has improving margins for the foreseeable future, with significant price elasticity.

Low rank example: A company that is in a challenged revenue environment with a fixed cost structure and limited ability to cut costs, indicating an outlook for declining margins.

Financial Leverage

A strict definition of financial leverage is total debt divided by total shareholder's equity. Financial leverage analysis is to determine the company's ability to improve shareholder value by means of utilizing its balance sheet to grow organically or to acquire assets. Analysts may look at the company's debt to cash flow leverage ratio, interest coverage ratios, or debt to equity ratios. In addition, the interest rate environment and the outlook for interest rates are a factor in determining the company's ability to manage financial leverage. Finally, the analyst is expected to determine the ability to service the debt given the industry and/or company profile, such as cyclicality, barriers to entry, history of bankruptcy, consistency in revenue and profit growth, or predictability in sales and profits and large cash reserves. The analyst is expected to take into account capital intensity of the company and the anticipated of capital allocation decisions.

High rank example: A company with predictable and growing revenue and cash flow with modest debt levels. This may indicate that the company could improve shareholder value through growth investments, including acquisitions, using debt financing.

Low rank example: A company in a cyclical industry in a late stage economic cycle that has above average debt leverage and is in an industry that has a history of financial challenges, including bankruptcies.

ANALYST CREDENTIALS, PROFESSIONAL DESIGNATIONS, AND EXPERIENCE

Senior Equity Research Analyst focusing on the Biotechnology and Specialty Pharmaceuticals industry. 16 years of industry experience. BA in Economics from Tulane University and an MBA from Columbia Business School. FINRA licenses 7, 24, 63, 86, 87

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NOBLE RATINGS DEFINITIONS	% OF SECURITIES COVERED	% IB CLIENTS
Outperform: potential return is >15% above the current price	89%	25%
Market Perform: potential return is -15% to 15% of the current price	11%	3%
Underperform: potential return is >15% below the current price	0%	0%

NOTE: On August 20, 2018, Noble Capital Markets, Inc. changed the terminology of its ratings (as shown above) from "Buy" to "Outperform", from "Hold" to "Market Perform" and from "Sell" to "Underperform." The percentage relationships, as compared to current price (definitions), have remained the same.

Additional information is available upon request. The recipient of this report who wishes further information regarding the subject company or the disclosure information mentioned herein, should contact by mail or phone.

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