Cadrenal Therapeutics

Tecarfarin Clinical Trial To Begin With Modified Design

Aug 07, 2025

Healthcare

CVKD

NASDAQ

Rating

Outperform

Unchanged

Current Price

$10.95

Target Price

$45.00

Market Capitalization
21.54m

Shares Outstanding
1.91m

Float
1.45m

Institutional Holdings
41.03%

12-Month Low/High
$5.70/$22.90

Average 90-Day Volume
30150

Fiscal Year End
12/31/2025

Revenues ($ MIL)			
Period	2023A	2024A	2025E
Q1	0.0	0.0	0.0A
Q2	0.0	0.0	0.0E
Q3	0.0	0.0	0.0E
Q4	0.0	0.0	0.0E
	0.0	0.0	0.0E

EPS ($)			
Period	2023	2024	2025E
Q1	(7.20)	(1.56)	(2.09)A
Q2	(1.28)	(2.24)	(1.48)E
Q3	(1.01)	(2.18)	(1.56)E
Q4	(16.01)	(2.55)	(1.75)E
	(9.29)	(8.73)	(6.64)E

Cadrenal Announces New Trial Design. Cadrenal announced that it plans to begin a trial testing tecarfarin in patients who are starting renal dialysis, both with and without atrial fibrillation (ESKD-Afib). This design reflects recent studies showing that the first several months after starting dialysis are an ultra-high risk period for mortality and cardiac events. The trial will test tecarfarin efficacy in reducing these events and could begin in late 2025 to early 2026.

Modified Study Design Focuses On Highest Risk Period. The initiation of renal dialysis impacts several important cardiovascular and renal functions. New studies show that the first six months after starting dialysis have a 20-fold increase in cardiovascular events and mortality. This has not previously been recognized due to pathologies of the underlying conditions that lead to CKD and dialysis.

Tecarfarin Was Developed As An Alternative To Current Drugs. The class of DOAC (direct oral anticoagulants, including Eliquis, Xarelto, and others) drugs is used for anticoagulation in cardiovascular conditions. Studies testing DOAC drugs for end-stage renal disease (ESRD) patients have not shown benefits but have higher safety risks. Previous clinical studies with tecarfarin have shown improvements in efficacy and the ability to maintain the patient within their target blood clotting ranges. This can reduce hospitalization rates, morbidity, and mortality.

Trial Could Begin Around Year-End 2025/Early 2026. We believe a pilot study could test about 20 to 30 patients, with arms stratified by atrial fibrillation or non-atrial fibrillation at baseline. The study is likely to follow the patients for the first 4 to 6 months to determine the effect of tecarfarin in reducing cardiovascular events and morbidities during this period. Data could be announced in 3Q26 to 4Q26.

Conclusion. We view the new trial design as an important development for tecarfarin. The new design focuses on a high-risk period with high mortality, where tecarfarin could show an improvement in patient outcomes as well as a reduction in cardiovascular events and hospitalizations. This contrasts to our previous expectations where tecarfarin would be tested in all dialysis patients with ESRD and atrial fibrillation. We are reiterating our Outperform rating and $45 price target.

Equity Research

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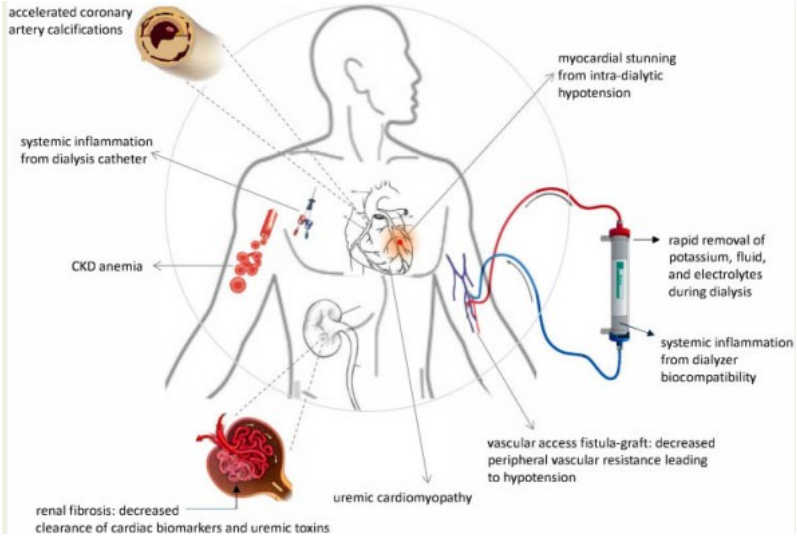
Summary: Cadrenal Announces New Trial Design. Cadrenal announced that it will begin enrolling patients into a trial testing tecarfarin in patients who are starting renal dialysis, both with and without atrial fibrillation (ESKD-Afib). This design modification correlates with recent studies showing that the first several months after patients begin dialysis is an ultra-high risk period for cardiac events such as stroke, myocardial infarct, and venous thromboembolism. The trial will test tecarfarin's efficacy in reducing these events and could begin in late 2025 to early 2026.

Background: Starting Dialysis Is A High Risk Period. When a chronic kidney disease patient's kidney function declines to end-stage disease levels, they require hemodialysis to filter their blood. Initiation of renal dialysis impacts several important cardiovascular and renal functions. As the blood passes through the dialysis equipment, it can activate the clotting cascade, leading to events such as heart attack, stroke, and thromboembolism.

New studies during the first six months of dialysis show it is a high-risk period with a 20-fold increase in cardiovascular events and mortality. This has not previously been recognized due to the underlying pathologies of the conditions that cause CKD and lead to dialysis. These patients typically have a combination of hypertension, diabetes, cardiovascular disease, along with a combination of secondary conditions.

Exhibit 1. Schematic Diagram of Dialysis Patients. Dialysis changes the pathophysiology of cardiovascular disease and changes its presentation, progression, and prognosis. The illustration shows some of the changes to the patient's body when initiating renal dialysis.



Source: Chan et al, The Cardiovascular–Dialysis Nexus: The Transition To Dialysis Is A Treacherous Time For The Heart. *European Heart Journal (2021) 42*, 1244–1253.

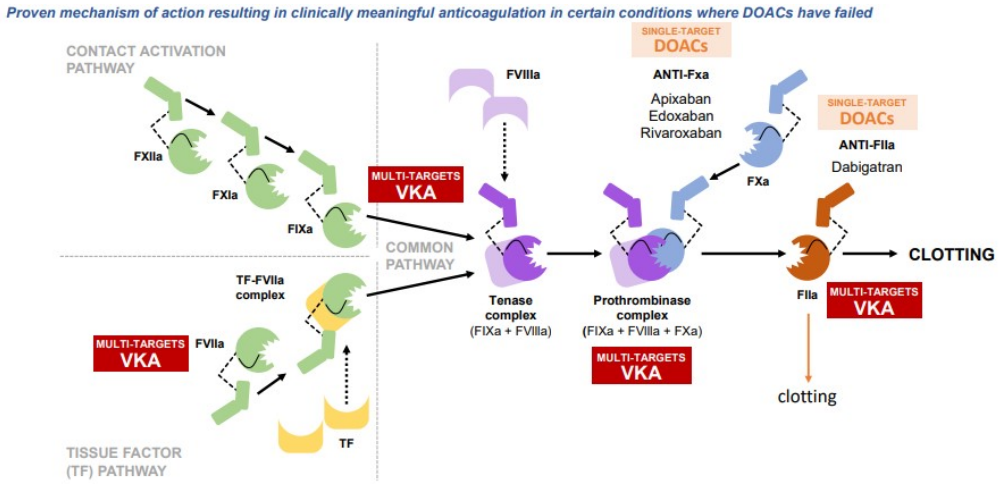
Tecarfarin Was Developed As An Alternative To Current Drugs. The class of DOAC (direct oral anticoagulants, including Eliquis, Xarelto, and others) drugs is used for anticoagulation in many cardiovascular conditions. Studies testing DOAC drugs for end-stage renal disease (ESRD) patients have not shown benefits but have higher safety risks. These drugs are mostly eliminated through the kidney, so that declining kidney function can result in drug accumulation and increase bleeding events. Although the DOAC category had over $29 billion in total FY2024 sales, they cannot be used in patients with ESKD-Afib as well as several other indications.

These patients can be treated with warfarin, a drug with variable efficacy that requires periodic patient monitoring. Previous clinical studies with tecarfarin have shown improvements in efficacy and the ability to maintain the patient within their target blood clotting ranges. This reduces hospitalization rates, morbidity, and mortality. Tecarfarin has received Orphan Drug Designation and Fast-Track Status for end-stage kidney disease patients and atrial fibrillation (ESKD-Afib).

Separately, Cadrenal is also developing tecarfarin in patients that are contra-indicated for DOACs. Tecarfarin has received Orphan Drug Designation for prevention of thromboembolism and thrombosis in patients with implanted mechanical support devices, such as left ventricular assist devices (LVADs). A second request for Orphan Drug Designation has been submitted for patients with chronic kidney disease who have an implanted mechanical heart valve that cannot take other drugs.

As discussed in our Research Note on March 5, Cadrenal and Abbott (ABT, Not Rated) made a collaborative agreement to develop tecarfarin in patients with Left Ventricular Assist Devices (LVADs). Abbott agreed to support the pivotal trial, to be known as the TECHLVAD trial (TECarfarin Anticoagulation and Hemocompatibility with Left Ventricular Assist Devices).

Exhibit 2. Targets Of The DOAC Drugs Compared With Vitamin K Antagonists. The DOAC (direct oral anticoagulants) drugs are targeted at one factor in the clotting cascade. Vitamin K antagonists (warfarin, tecarfarin) affect several clotting factors.



Source: Cadrenal Therapeutics, Inc.

New Trial Will Test Tecarfarin During The Highest Risk Period. In addition to the many changes to heart demand, blood pressure, kidney function, and electrolyte balance, the dialysis process circulates blood equipment that exposes it to factors that can start the coagulation cascade. This can lead to clotting-related complications, including myocardial infarction, stroke, and thromboembolism. The new trial is being designed to test tecarfarin during the high-risk transition period when patients start dialysis.

Exhibit 3. High Risk Period. Studies have established that CKD doubles cardiovascular risk, but the underlying conditions that lead to CKD have hidden the high risk of cardiovascular death after the initiation of dialysis. The data below show that the risk level increases to over 20-times higher than average for the US population during the initial four-month period after the start of renal dialysis. This high cardiovascular risk is seen during the first 4 months of dialysis.

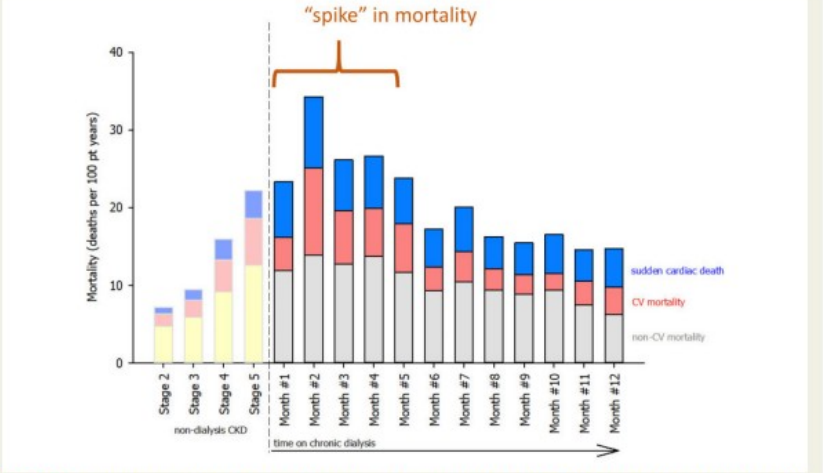


Figure 1 Standardized mortality rates in the chronic kidney disease and dialysis population, Medicare 5% CKD sample (2011–2014). Our analysis of a 5% random sample of Medicare claims highlights 'the spike' in cardiovascular mortality that occurs when dialysis starts that extends into the first 4 months of chronic dialysis. Direct standardized rates for age, gender, and race were calculated as per methods outlined by Ahmad *et al.*[2] See Supplementary material online for details regarding the generation of this figure.

Source: Chan et al, The Cardiovascular–Dialysis Nexus: The Transition To Dialysis Is A Treacherous Time For The Heart. European Heart Journal (2021) 42, 1244–1253.

The Trial Could Begin Around Year-End 2025/Early 2026. We believe a pilot study with about 20 to 30 patients, with arms stratified by patients with or without atrial fibrillation at baseline. The study is likely to follow the patients for the first 4 to 6 months to determine the effect of tecarfarin to reduce the cardiovascular events and morbidities during this period. This would allow data to be announced around 3Q26 to 4Q26.

Conclusion. We view the new trial design as an important development for tecarfarin. The new design focuses on a high-risk period with high mortality, where tecarfarin could show an improvement in patient outcomes during the most critical period. The trial endpoints could show a reduction in cardiovascular events and hospitalizations, demonstrating the importance of an effective anti-coagulant in this population. This contrasts to our previous expectations where tecarfarin would be tested in all dialysis patients with ESRD and atrial fibrillation. We are reiterating our Outperform rating and $45 price target.

Company Profile

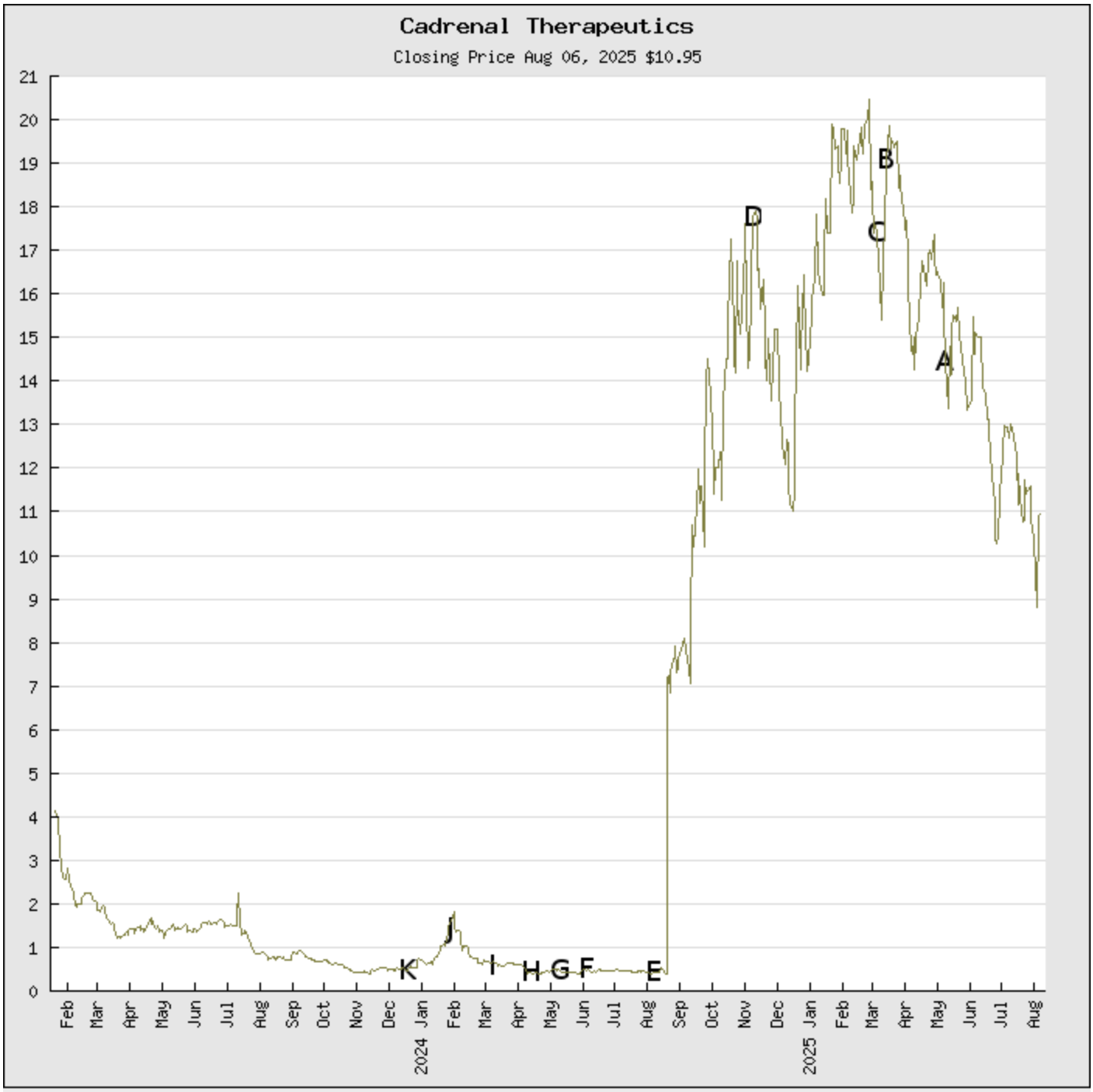
Cadrenal is a biopharmaceutical company developing tecarfarin, an oral anticoagulant for prevention of systemic thromboembolism (blood clots) in patients with rare medical conditions. The lead indication is for patients with end-stage kidney disease (ESKD) with atrial fibrillation (irregular heartbeat, AFib), an orphan indication currently in the Phase 3 design stage. Additional potential pipeline orphan indications include patients with left ventricular assist devices (LVAD) and antiphospholipid syndrome (APS).

Fundamental Analysis

In our analysis, we give Cadrenal Therapeutics a rating of 4.0 checks out of 5 checks. This falls in the upper half of our "above average" range. Our positive fundamental rating is based on the company's position to introduce a new drug for an unserved orphan market. For further explanation of our fundamental analysis, please refer to the disclosures at the end of this report.

Valuation Summary

Our models are based on the Phase 3 ACTOR-AF trial beginning in 2H25. Patient enrollment is expected to take about 12 to 18 months, with results in 2H27. We allow additional time for data analysis, filing an application with the FDA, with product launch in 2028. Based on our estimates of the target patient populations, we estimate FY2029 EPS of $8.55 per share. We discount these earnings at 35% per year and assign a multiple of 15X for a price target of $45 per share.



A - 05/09/2025 Outperform Target $45.00 Current $14.45
B - 03/14/2025 Outperform Target $45.00 Current $19.09
C - 03/05/2025 Outperform Target $45.00 Current $17.40
D - 11/08/2024 Outperform Target $45.00 Current $17.74
E - 08/08/2024 Outperform Target $4.00 Current $0.43
F - 06/05/2024 Outperform Target $4.00 Current $0.51
G - 05/10/2024 Outperform Target $4.00 Current $0.46
H - 04/12/2024 Outperform Target $4.00 Current $0.41
I - 03/13/2024 Outperform Target $4.00 Current $0.59
J - 02/01/2024 Outperform Target $4.00 Current $1.41
K - 12/18/2023 Outperform Target $4.00 Current $0.48

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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.

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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	86%	14%
Market Perform: potential return is -15% to 15% of the current price	14%	5%
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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