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Tonix Pharmaceuticals

Oct 11, 2024

A New Era For Tonix Begins With The Tonmya NDA Filing

Healthcare

TNXP

NASDAQ

Rating

Outperform

Unchanged

Current Price

$0.14

Target Price

$1.50

Market Capitalization
3.1M

Shares Outstanding
11M

Float
21M

Institutional Holdings
0.3%

12-Month Low/High
$0.12/$22.14

Average 90-Day Volume
33390000

Fiscal Year End
12/31/2024

We Expect The NDA Filing For Tonmya Approval To Be Submitted Shortly. We anticipate the NDA submission for Tonmya to be announced around the end of October 2024. This would start the FDA review process, which we expect to lead to marketing approval in mid-2025. In July, Tonmya received Fast Track Review, a designation that gives advantages in the regulatory pathway. With a pending NDA submission for a drug that could be used by millions of patients, we believe the company's progress has not been reflected in the stock price.

Fast Track Review Is A Significant Distinction. The Fast Track Review designation from the FDA is awarded to drugs that can make significant impact on serious medical conditions. The designation provides important benefits including increased communications with the FDA, as well as eligibility for Accelerated Approval and Priority Review. We expect the application for Accelerated Approval to be filed shortly after the NDA is completed. This could shorten the FDA's review period by up to 4 months.

Phase 3 RESILIENT Trial Met Its Primary and All Secondary Endpoints. The Phase 3 RESILIENT study was a double-blind placebo-controlled study enrolling 457 patients with fibromyalgia. Patients received either placebo or one 2.8mg tablet for the first two weeks, followed by two tablets (5.6mg total) for the remaining 12 weeks. The primary endpoint was reduction in pain severity score compared with placebo. Secondary endpoints included sleep quality, reducing fatigue, overall symptoms and function. The Primary and Secondary Endpoints were met with high statistical significance of ($p<0.001$ or lower).

Tonmya Phase 3 Studies Justified Fast Track Designation From The FDA. To be awarded Fast Track Review, a drug must show advantages over available therapies. This can include superior effectiveness or an improved side effect profile. In addition to its effects on sleep, fatigue, and function, Tonmya has shown clinical benefits in pain relief that could reduce the need for other medications, including opioid or non-opioid pain medications.

Conclusion. The fibromyalgia patient population is estimated at over 10 million adults, with an estimated 22 million annual prescriptions for its symptoms. As a condition with no effective therapy, we believe Tonix could achieve significant use upon introduction. We are reiterating our Outperform rating and $1.50 price target.

Revenues ($ MIL)

Period	2023A	2024E	2025E
Q1	0.0	3.9E	4.2E
Q2	0.0	3.9E	4.3E
Q3	4.0	4.0E	4.3 E
Q4	3.8	4.1E	4.4 E
	7.8	15.8E	17.2 E

EPS ($)

Period	2023A	2024E	2025E
Q1	(3.20)	(0.47)E	(0.20)E
Q2	(3.63)	(0.23)E	(0.21)E
Q3	(1.57)	(0.23)E	(0.23)E
Q4	(0.47)	(0.24)E	(0.23)E
	(6.85)	(1.11)E	(0.87)E

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A New Era For Tonix Begins With The Tonmya NDA Filing

We anticipate the NDA submission for Tonmya to be announced around the end of October 2024. This would start the FDA review process, which we expect to lead to marketing approval in mid-2025. In July 2024, Tonmya received Fast Track Review, a designation that gives advantages during the regulatory review process. With a pending NDA submission for a fibromyalgia drug that could be used by millions of patients, we believe the company's progress has not been reflected in the stock price.

Fast Track Review Is A Significant Distinction. The Fast Track Review designation is awarded to drugs that the FDA believes can make significant impact on serious medical conditions with unmet needs. It is only awarded to drugs that provide novel therapy where none exists and/or has meaningful advantages over existing therapies. We believe the Phase 3 clinical data shows Tonmya meets both requirements.

To be awarded Fast Track Review, a drug must show advantages over available therapies. This can include superior effectiveness or an improved side effect profile. In addition to its effects on sleep, fatigue, and function, Tonmya has shown clinical benefits in pain relief that could reduce the need for other medications, including opioid or non-opioid pain medications.

Fast Track Review allows more frequent meetings and written communications with the FDA. After submission, the increased communications help questions and issues to be resolved quickly, often leading to earlier drug approval and access by patients. The designation also makes Tonmya eligible for Accelerated Approval and Priority Review. We expect the application for Accelerated Approval to be filed after the NDA is completed. This could shorten the FDA's review period by up to four months.

Fast Track Status Shows That FDA Recognizes Fibromyalgia As An Unmet Medical Need. When fibromyalgia was initially described as a new condition, it was not well-defined and lacked specific diagnostic characteristics. It has inconsistent combinations of physical and cognitive symptoms that include chronic pain, insomnia, depression, brain fog, fatigue, and abdominal cramps with varying severity. Some questioned whether it was a separate condition, or effects of other conditions and a diagnosis of exclusion.

Fibromyalgia patients are often treated with multiple drugs for its neurological or cognitive symptoms, including opioid pain medications. This designation shows the FDA recognizes fibromyalgia to be a serious condition that has no effective treatments.

Phase 3 RESILIENT Trial Met Its Primary and All Secondary Endpoints. The Phase 3 RESILIENT study was a double-blind placebo-controlled study enrolling 457 patients with fibromyalgia. Patients received either placebo or one 2.8mg tablet for the first two weeks, followed by two tablets (5.6mg total) for the remaining 12 weeks.

The primary endpoint was reduction in pain severity score compared with placebo. Secondary endpoints included sleep quality, reducing fatigue, overall symptoms and function. The Primary Endpoint, reduction in pain, and all Secondary Endpoints were met with high statistical significance of ($p<0.001$ or lower).

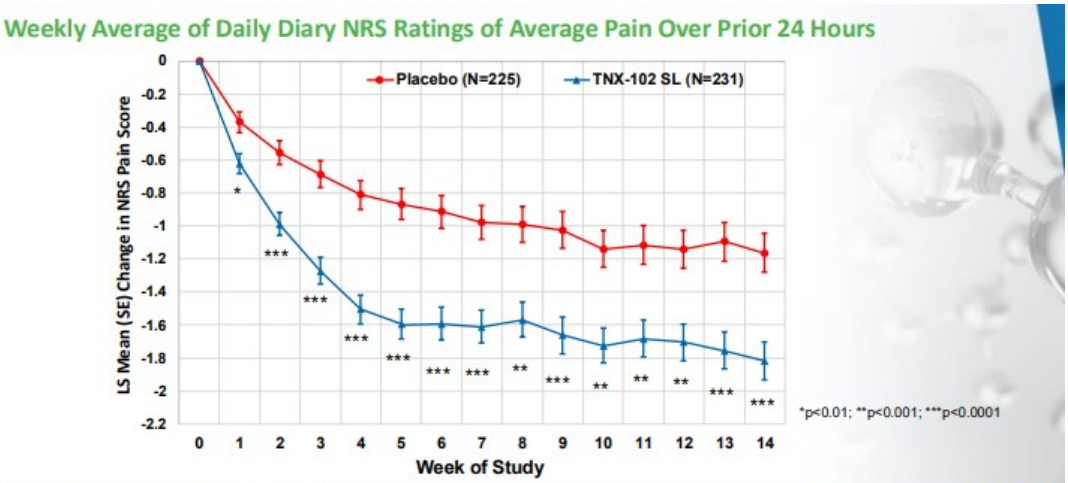
The data shows pain scores for the two groups began to separate in after just one week of the trial, with ($p<0.001$) at each week. The pain score differences widening over the 14-week duration of the study, reaching an effect size of 0.38 with ($p<0.001$). Patients showing at least 30% pain reduction reached 45.9% for the treatment group and 27.1% for the placebo group ($p<0.001$). Patients showing at least 30% pain reduction reached 45.9% for the treatment group and 27.1% for the placebo group ($p<0.001$).

Exhibit 1. The RESILIANT Trial Met All Of Its Primary and Secondary Endpoints With High Statistical Significance.

Endpoint	P-value	Effect Size (ES)
Primary Endpoint		
Daily Diary Pain ratings	$p = 0.00005$	ES = 0.38
Key Secondary Endpoints		
Patient Global Impression of Change (PGIC), responders	$p = 0.00013$	--
Fibromyalgia Impact Questionnaire – Symptoms domain	$p = 0.000002$	ES = 0.44
Fibromyalgia Impact Questionnaire – Function domain	$p = 0.001$	ES = 0.30
PROMIS Sleep Disturbance instrument	$p = 0.0000001$	ES = 0.50
PROMIS Fatigue instrument	$p = 0.00009$	ES = 0.37
Diary Sleep Quality ratings	$p = 0.0007$	ES = 0.32

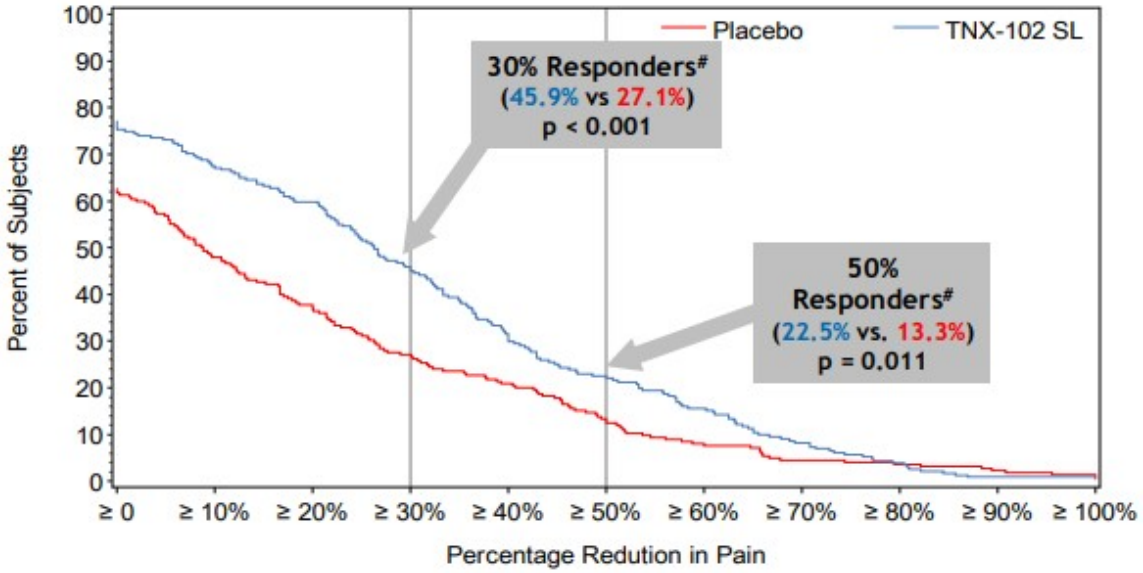
Source: Tonix Pharmaceutical Holdings, Inc.

Exhibit 2. RESILIENT Primary Outcome Measure Reduction in Widespread Pain. The pain scores for TNX-102 SL compared with placebo began to show significant differences at week 1 and increased over the 14 weeks of the study.



Source: Tonix Pharmaceutical Holdings, Inc.

Exhibit 3. RESILIENT Continuous Pain Responder Analysis Favors TNX-102 SL. Patients showing a 30% reduction in pain reached 45.9% (p<0.001) compared with 27.1% for the placebo group. Patients reaching 50% reduction in pain reached 22.5% (p<0.011) compared with 13.3% for the placebo group.



Source: Tonix Pharmaceutical Holdings, Inc.

New Trial Will Test Tonmya In ASR/ASD. A poster presentation at the American Society of Clinical Psychopharmacology (ASCP) Annual Meeting in May 2024 discussed the design of the proposed Phase 2 OASIS trial in civilians that had been in motor vehicle accidents. The endpoints are reduction in the acute stress reaction (ASR), the frequency of acute stress disorder (ASD), and posttraumatic stress disorder (PTSD). The trial will test Tonmya in a civilian population immediately after the traumatic event, controlling several variables that we believe made previous military PTSD trials miss their endpoints.

Conclusion. The fibromyalgia patient population is estimated at over 10 million adults, with an estimated 22 million annual prescriptions for its symptoms. As a condition with no effective therapy, we believe Tonix could achieve significant use upon introduction. We are reiterating our Outperform rating and $1.50 price target.

Company Profile

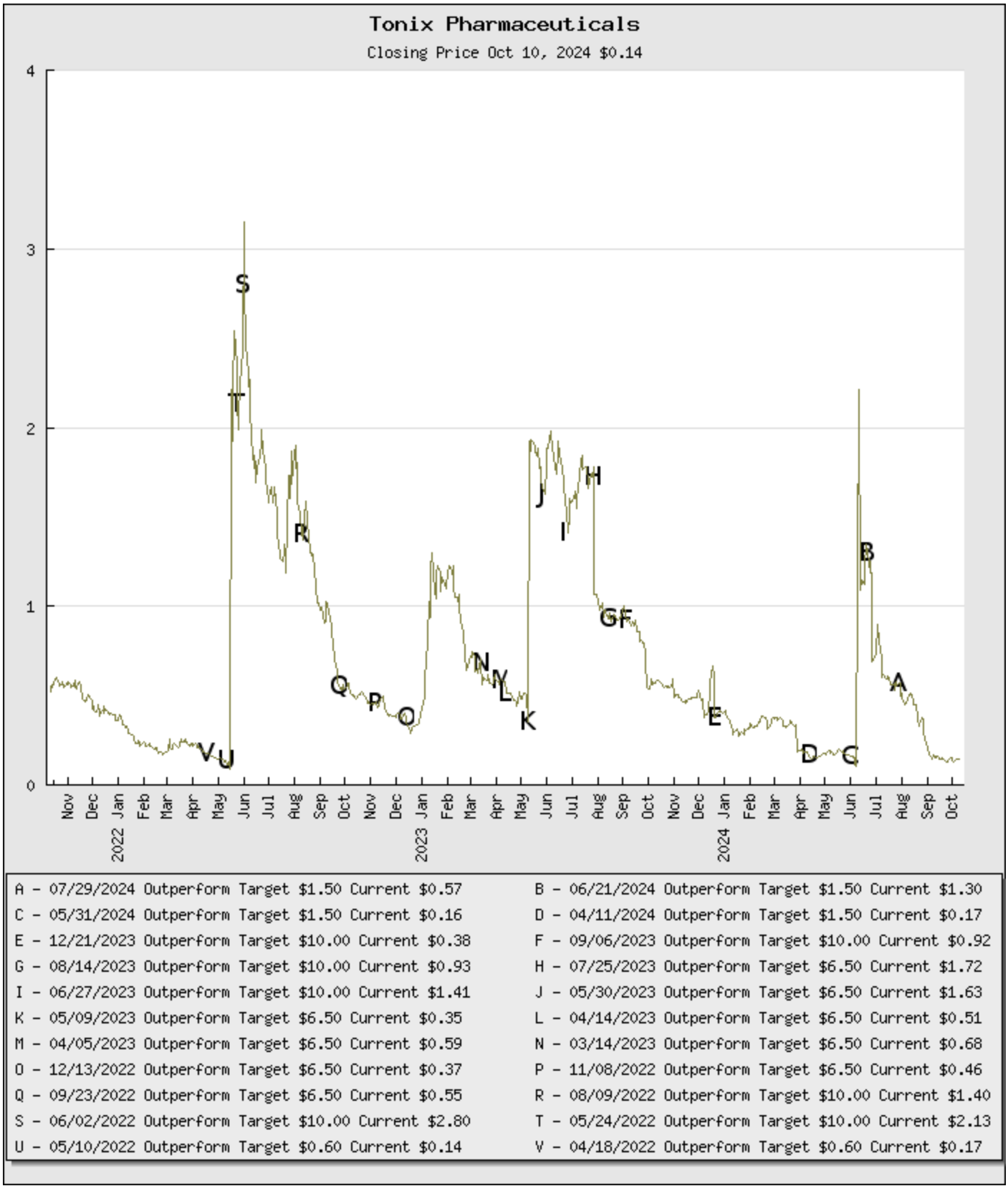
Tonix is a biopharmaceutical company developing therapeutics in immunology, infectious diseases, and central nervous system (CNS) disorders. Its products are for conditions with immunological and/or neurological components in several disease areas. These products have been based on both its internal research and in-licensing for development. Its most advanced product, TNX-102 SL is in a Phase 3 clinical trial for fibromyalgia. Other programs are in COVID-19, infectious disease, transplantation, cancer, and biodefense.

Fundamental Analysis; 3.5/5.0 Checks

Based on our analysis, we give TNXP 3.5 out of 5.0 checks. This falls in our "above average" range of 3.5 to 4.0 checks. The company's executives, advisors, and collaborators at research institutions are accomplished scientists with experience in drug development to guide the products through clinical trials to the market. For a further explanation of our fundamental analysis, please refer to the disclosures at the end of this report.

Valuation Summary

TNXP is currently trading at a market capitalization of about $10.0 to $15.0 million. Its balance sheet as of December 31, 2023 had $24.9 million in cash, excluding the $4.4 million raised in March 2024. This is below its cash level, and does not reflect the potential of a novel drug for fibromyalgia. We consider this to be below fair value, and see a 2x to 5X multiple of cash as a low multiple for biotechnology companies. Our adjusted price target is $1.50 per share.


Tonix Pharmaceuticals
Closing Price Oct 10, 2024 $0.14
4
3
2
1
0
Nov
Dec
Jan
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Jun
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Aug
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Sep
Oct
2022
2023
2024
A - 07/29/2024 Outperform Target $1.50 Current $0.57
B - 06/21/2024 Outperform Target $1.50 Current $1.30
C - 05/31/2024 Outperform Target $1.50 Current $0.16
D - 04/11/2024 Outperform Target $1.50 Current $0.17
E - 12/21/2023 Outperform Target $10.00 Current $0.38
F - 09/06/2023 Outperform Target $10.00 Current $0.92
G - 08/14/2023 Outperform Target $10.00 Current $0.93
H - 07/25/2023 Outperform Target $6.50 Current $1.72
I - 06/27/2023 Outperform Target $10.00 Current $1.41
J - 05/30/2023 Outperform Target $6.50 Current $1.63
K - 05/09/2023 Outperform Target $6.50 Current $0.35
L - 04/14/2023 Outperform Target $6.50 Current $0.51
M - 04/05/2023 Outperform Target $6.50 Current $0.59
N - 03/14/2023 Outperform Target $6.50 Current $0.68
O - 12/13/2022 Outperform Target $6.50 Current $0.37
P - 11/08/2022 Outperform Target $6.50 Current $0.46
Q - 09/23/2022 Outperform Target $6.50 Current $0.55
R - 08/09/2022 Outperform Target $10.00 Current $1.40
S - 06/02/2022 Outperform Target $10.00 Current $2.80
T - 05/24/2022 Outperform Target $10.00 Current $2.13
U - 05/10/2022 Outperform Target $0.60 Current $0.14
V - 04/18/2022 Outperform Target $0.60 Current $0.17

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Noble intends to seek compensation for investment banking services and non-investment banking services (securities and non-securities related) within the next 3 months.

Noble is not a market maker in the Company.

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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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Outperform: potential return is >15% above the current price	90%	25%
Market Perform: potential return is -15% to 15% of the current price	10%	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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