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Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP)

February 28, 2024

BUY: Better Sleep Equals Less Pain, A New Treatment for Fibromyalgia: Tonmya, Re-tasking Via 505b2, NDA Filing 2H24

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Tonix Pharmaceuticals plans to file an NDA (2H24) for Tonmya, a 505b2 sublingual formulation of cyclobenzaprine for Fibromyalgia (chronic pain). The NDA is supported by multiple (three) pivotal trials. Outstanding warrants, if exercised, can potentially bring in \$129M in additional capital. Launching with a Buy Rating and \$3.0 target.

Investment Highlights

Tonmya – 505B2 – Low Risk, High Potential Reward. The Fibromyalgia space represents 6-12 million adults, primarily women in the US. FDA-approved drugs include Lyrica, Cymbalta, and Savella (approved a decade plus) ago and re-purposed). A high failure rate (60%) has been reported with existing therapies, and all have known side effects. Tonmya has been evaluated in three Phase III trials, RELIEF, RALLY and RESILENT. The RELIEF (2020) trial met its primary endpoint as did the RESILENT trial (2023). RALLY missed as the trial was plagued by discontinuations because of the COVID effect. Tonix expects to file the NDA 2H-24 with an FDA decision by 2H25. We view the outcome as low risk as the drug, cyclobenzaprine, has been well-established (505b2 pathway) for skeletal muscle pain/injury. Additional indications beyond FM exist from Long COVID to Acute Street Reaction/Disorders but we do not factor them into our model.

What is Fibromyalgia (FM)? FM is a chronic syndrome characterized by widespread musculoskeletal pain accompanied by fatigue, sleep, memory, and mood issues. The peak incidence of FM occurs between 20-50 years of age, and 70% of diagnosed patients are female. According to the American Chronic Pain Association, an estimated six to twelve million adults in the U.S. have FM.

Migraine Too: Zembrace (injection) and Tosymra (Nasal): These represent two marketed migraine drugs being sold today by Tonix. We expect the combined sales of both drugs (annually in 2025), to reach close to \$30M and grow modestly to just \$43M by 2030. Imitrex nasal is being discontinued and that may benefit Tonmya too. More importantly, we see the company as leveraging the product offerings as a “test drive” towards developing the sales infrastructure to support the launch of Tonmya.

Valuation: Our valuation for Tonix Pharmaceuticals is driven by Tonmya in Fibromyalgia. We project our model through 2030 and select a 30% discount rate. We assume a capital raise and out-year dilution (including all warrants are exercised). These assumptions flow through our FCFE, dEPS and SOP models which are averaged and rounded to the nearest whole number to derive our 12-month price target of \$3.00

Risks to our thesis include: 1. Regulatory Approvals; 2. Market Share Success and Pricing Assumptions; 3. Financing Risk; 4. Expense Control; 5. Human Capital; 6. Intellectual Property.

Current Price \$0.37
Price Target \$3.00



Source: Tonix

Stock Data			
52-Week Range	\$0.26	-	\$4.94
Shares Outstanding (mil.)	81		
Market Capitalization (mil.)	\$30		
Enterprise Value (mil.)	\$30		
Debt to Capital	0%		
Book Value/Share	\$62,876		
Price/Book	0.1		
Average Three Months Trading Volume (K)	247		
Insider Ownership	0.0%		
Institutional Ownership	20.8%		
Short interest (mil.)	0.0		
Dividend / Yield	\$0.00/0.0%		

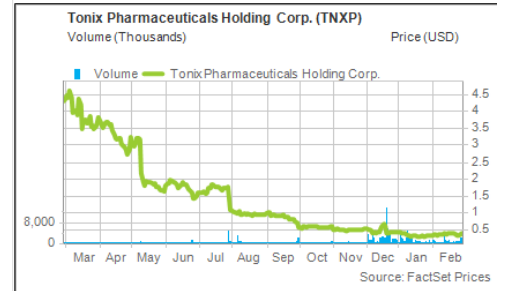


Exhibit 1. Milestones and catalysts for Tonix Pharmaceuticals

Key Clinical Programs

Molecule*	Indication	Phase 1	Phase 2	Phase 3	NDA Submission
Tonmya™	Fibromyalgia		Positive Phase 3 Topline Results Reported 4Q'23		Submission expected 2H'24
TNX-102 SL Cyclobenzaprine HCl Protectic® Sublingual Tablets	Long COVID		Phase 2 Topline Results Reported 3Q'23		
	Acute Stress Disorder		Phase 2 Study Start Expected 1Q'24		
TNX-1300 Cocaine Esterase NIDA Funded	Cocaine Intoxication		Phase 2 Study Start Expected 1Q'24		
TNX-2900 Intranasal Potentiated Oxytocin FDA Orphan Drug Designation	Prader-Willi Syndrome		Phase 2 Ready		
TNX-1500 Anti-CD40L mAb	Organ Transplant Rejection/ Autoimmune Conditions	Phase 1 Study Ongoing	Phase 1 data expected 3Q'24		

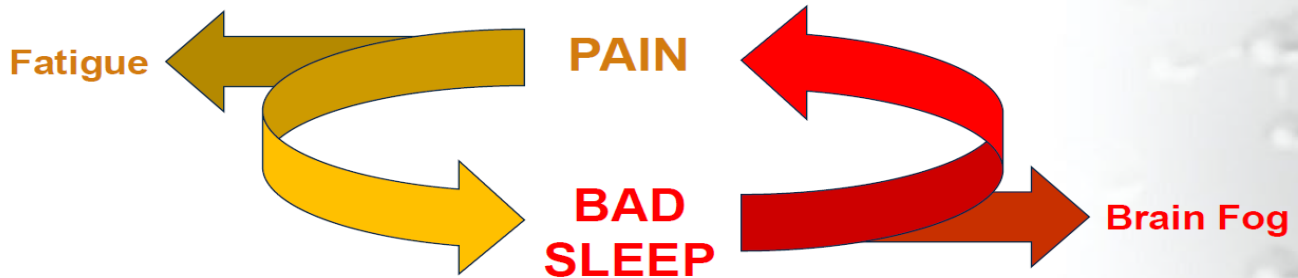
*All of Tonix's product candidates are investigational new drugs or biologics and none has been approved for any indication.

Source: Tonix Pharmaceuticals

Exhibit 2. Tonmya MOA is simple – Better Sleep w/o Side Effects.

Poor Sleep and Pain have Bi-directional Reinforcing Effects¹

- **Poor sleep and pain form a vicious cycle in driving fibromyalgia decompensation**
 - Can't sleep → worse pain / In pain → can't sleep
 - Poor sleep and pain contribute to persistence, chronicity and severity
 - Syndrome includes symptoms of fatigue and brain fog
- **Treating sleep disturbance in fibromyalgia has the potential to break the vicious cycle**
 - Potential to remove an obstacle to recovery
 - Using the right medicine is important – some sedative/hypnotics don't work^{1,2}



¹Moldofsky H, et al. *J Rheumatol*. 1996;23:529–533.
²Grönald M, et al. *Clin Rheumatol*. 1993;12(2):186–191

Source: Tonix Pharmaceuticals

Exhibit 3. Does it work? Three clinical trials are being submitted as part of the NDA in 2H-2024. The RESILIENT trial below shows a sharp separation between active and control groups with significance. Given the long and well-documented history of Cyclobenzaprine, we see low approval risk.

Summary of Key Pre-Specified Secondary Outcome Measures

<u>Rating Scale</u>	<u>Week 14</u>	<u>Met**</u>
Patient Global Impression of Change (PGIC)	$p < 0.001$	✓
Fibromyalgia Impact Questionnaire - Symptoms	$p < 0.001$	✓
Fibromyalgia Impact Questionnaire - Function	$p = 0.001$	✓
PROMIS Sleep Disturbance	$p < 0.001$	✓
PROMIS Fatigue	$p < 0.001$	✓
Weekly average of daily Sleep Quality scores	$p < 0.001$	✓

*In order of statistical serial gate-keeping hierarchy (or, "waterfall") to control overall Type 1 error

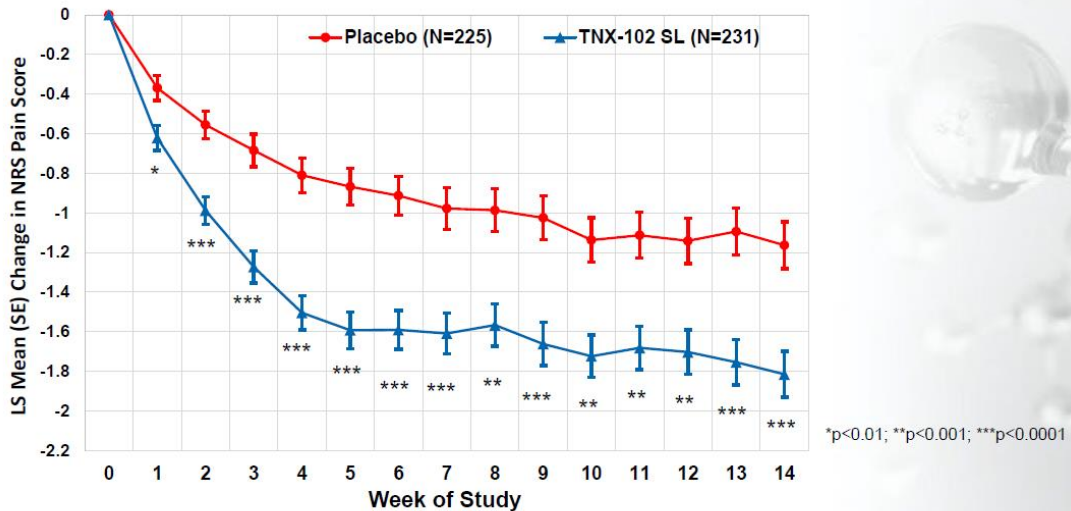
**Statistical significance met

Source: Tonix Pharmaceuticals

RESILIENT Primary Outcome Measure Reduction in Widespread Pain



Weekly Average of Daily Diary NRS Ratings of Average Pain Over Prior 24 Hours



Week 14 LS mean (SE) change from baseline for TNX-102 SL -1.82 (0.12) and for placebo -1.16 (0.12); LSMD from placebo -0.65 (0.16); $p=0.00005^{\#}$

[#]Based on Mixed Model Repeated Measures with Multiple Imputation, with fixed categorical effects of treatment, center, study week, and treatment by study week interaction, as well as baseline value and baseline value-by-study week interaction. Abbreviations: LS, least squares; LSMD, least squares mean difference; NRS, numerical rating scale; SE, standard error

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Source: Tonix Pharmaceuticals

Exhibit 4. Warrants Outstanding Represent up to \$129 Million in Cash to the Company. We assume dilution in our model for valuation purposes.

	Number of Warrants	Exercise Price	Cash upon exercise	Grant Date	Expiry	Shares outstanding if exercised
	9,000,000	\$0.50	\$4,500,000	10/3/2023	10/03/24	89,816,395
	81,081,081	\$0.555	\$45,000,000	12/22/2023	12/22/25 ³	170,897,476
	9,000,000	\$0.50	\$4,500,000	10/3/2023	10/03/28	179,897,476
	81,081,081	\$0.85	\$68,918,919	12/22/2023	12/22/28	260,978,557
	7,000,000	\$1.00	\$7,000,000	8/1/2023	08/01/28	267,978,557
Total	187,162,162		\$129,918,919			

Source: Tonix Pharmaceuticals

Model & Assumptions

1. We assume an actionable market prevalence of 6 million persons.
2. We assume an NDA filing in 2H24 followed by approval and launch in late 2025, with no related revenues in 2025.
3. We assume the sublingual formulation results in specialized pricing (above generics) for a \$5,000 annual cost of therapy with a low cost of goods of 10% initially and with volume, over time dropping to just 7%.
4. We assume a modest market share penetration of just 0.5% in 2026 rising to only 2.5% by 2030 coupled with annual pricing of \$5,000. Our pricing assumption could prove conservative however in a market where generic Cyclobenzaprine is available, we feel any higher pricing could hurt market share penetration.
5. Migraine Franchise: We assume the franchise will grow at 15% for the next two years and then moderate down to single digits for peak revenues of just \$43M by 2030.

Exhibit 5. Market Model TNX-102 SL for Fibromyalgia

TNX-102 SL for Fibromyalgia	2025E	2026E	2027E	2028E	2029E	2030E
Fibromyalgia Prevalence - Active Seeking	5,960,000	6,120,000	6,280,000	6,440,000	6,600,000	6,760,000
Increase in Incidence	160,000	160,000	160,000	160,000	160,000	160,000
Market Penetration	0.00%	0.50%	1.00%	1.75%	2.00%	2.50%
Total Patients Treated	-	30,600	62,800	112,700	132,000	169,000
Annual Cost of Treatment	\$ 5,308	\$ 5,361	\$ 5,414	\$ 5,468	\$ 5,523	\$ 5,578
Increase in Cost	1%	1%	1%	1%	1%	1%
Total Revenue ('000)	\$ -	\$ 164,037	\$ 340,017	\$ 616,292	\$ 729,051	\$ 942,740

Source: Dawson James.

Valuation Model Assumptions:

Our approach to modeling Tonix is primarily valued on Tonmya and our market assumptions are for moderate success, specifically single-digit market share (see Tomya assumptions on the prior page). We assume warrants are exercised and do bring in \$129M in capital (267M additional shares). We also assume additional capital raises this year (before warrants are exercised). Given the small, capitalized nature of Tonix, we assume our maximum discount rate of 30% and apply this rate in our free cash flow to the firm (FCFF), Discounted EPS (dEPS), and Sum of the Parts (SOP) models. Our model is based on a fully diluted share count in 2030. These three models' results are averaged and rounded to the nearest whole number to derive our 12-month price target.

Exhibit 6. Free Cash Flow Model.

Average	3
Price Target	2
Year	2024

DCF Valuation Using FCF (mln):

units ('000)	2023A	2024E	2025E	2026E	2027E	2028E	2029E	2030E
EBIT	(118,951)	(120,666)	(86,846)	58,278	244,779	524,714	635,823	834,215
Tax Rate	0%	0%	10%	15%	25%	30%	31%	32%
EBIT (1-t)	(118,951)	(120,666)	(78,162)	49,536	183,584	367,300	438,718	567,266
CapEx		-	-	-	-	-	-	-
Depreciation								
Change in NWC								
FCF		(120,666)	(78,162)	49,536	183,584	367,300	438,718	567,266
PV of FCF	-	(120,666)	(60,124)	29,312	83,561	128,602	118,159	117,524
Discount Rate	30%							
Long Term Growth Rate	1%							
Terminal Cash Flow	1,975,650							
Terminal Value YE2030	409,308							
NPV	705,676							
NPV-Debt	0							
Shares out ('000)	315240							
NPV Per Share	2.24							

Source: Dawson James.

Exhibit 7. Discounted-EPS Model.

Current Year	2024
Year of EPS	2030
Earnings Multiple	10
Discount Factor	30%
Selected Year EPS	1
NPV	2.43

Source: Dawson James Estimates

		Discount Rate and Earnings Multiple Varies, Year is Constant						
		2.43	5%	10%	15%	20%	25%	30%
Earnings Multiple	1	0.9	0.7	0.5	0.4	0.3	0.2	
	5	4.4	3.3	2.5	2.0	1.5	1.2	
	10	8.8	6.6	5.1	3.9	3.1	2.4	
	15	13.1	9.9	7.6	5.9	4.6	3.6	
	20	17.5	13.3	10.2	7.9	6.2	4.9	
	25	21.9	16.6	12.7	9.8	7.7	6.1	
	30	26.3	19.9	15.2	11.8	9.2	7.3	
	35	30.7	23.2	17.8	13.8	10.8	8.5	

Source: Dawson James.

Exhibit 8. Sum-of-the-Parts Model.

	LT Gr	Discount Rate	Yrs to Mkt	% Success	Peak Sales (MM's)	Term Value
TNX-102 Fibromyalgia	1%	30%	2	70%	\$943	\$3,251
NPV						\$2
Migraine Franchise	1%	30%	0	100%	\$50	\$172
NPV						\$0
Other Pipeline	1%	30%	3	70%	\$200	\$690
NPV						\$0
Antiviral Discovery Paltform	1%	30%	5	30%	\$1,000	\$3,448
NPV						\$0
Net Margin						50%
MM Shrs OS (2030E)						315
Total						\$3.20

Source: Dawson James.

Risk Analysis

1. Clinical Risk. There can be no assurances that the company's lead product will be submitted on time and if submitted and accepted will be approved.
2. Market Share Risk. There can be assurances that the company's lead product will be successful at penetrating the marketplace.
3. Pricing Risk: There can be no assurances that our pricing assumption is accurate, especially when one considers the availability of generic versions, and oral formulations of the drug, which are "cheaper".
4. Financing Risk. There can be no assurances that the company can successfully raise capital to continue current operations and that the existing warrants will be successfully exercised.
5. Expense Control. There can be no assurances that our assumption that the company reduces expenses in the out-years is accurate.
6. Human Capital. There can be no assurance that the current management team remains in place and that the company is successfully building the required sales infrastructure to support its product offerings.
7. Intellectual Property. There can be no assurance that the company's current IP protections will work around its lead products and not be overturned or penetrated.

Please see the company's disclosures in the annual report for additional associated risks.

Exhibit 9. Income Statement.

Tonix Pharmaceuticals - Income Statement (\$000)																	
YE December 31	2022A	1Q23A	2Q23A	3Q23A	4Q23E	2023E	2024E	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E
Revenue:																	
TNX-102 for Fibromyalgia	-	-	-	-	-	-	-	-	-	-	-	-	164,037	340,017	616,292	729,051	942,740
Migraine Franchise - Zembrace & Tosmyra	-	-	-	-	-	-	-	6,900	7,200	7,800	8,100	30,000	34,500	39,675	41,659	42,492	43,342
TNX-102 Other Indications - Long Covid & Acute Stress Disorder	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-1300 (Cocaine Esterase) - Cocaine Intoxication	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-2900 (Intranasal Oxycotin) - Prader Willy Syndrome	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
TNX-1500 (Anti-CD40L mAb) - Organ Rejection	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Antiviral Discovery Platform	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net revenue	-	-	-	3,989	-	-	-	6,900	7,200	7,800	8,100	30,000	198,537	379,692	657,950	771,543	986,082
Collaborative revenue:	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Collaborative Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	3,989	-	-	-	6,900	7,200	7,800	8,100	30,000	198,537	379,692	657,950	771,543	986,082
Expenses:																	
Costs of Goods Sold	-	-	-	2,374	-	-	-	690	720	780	810	3,000	19,854	34,172	52,636	54,008	69,026
Research and Development	81,876	26,511	21,976	21,050	20,000	89,537	89,537	15,445	16,117	16,788	18,803	67,153	50,365	30,000	30,600	31,212	31,836
General and Administrative	30,215	7,391	7,026	8,712	8,000	31,129	31,129	10,740	11,206	11,673	13,074	46,694	70,040	70,741	50,000	50,500	51,005
Total Expenses	112,091	33,902	29,002	32,136	28,000	120,666	120,666	26,875	28,043	29,242	32,687	116,846	140,258	134,913	133,236	135,720	151,867
Operating Income (Loss)	(112,091)	(33,902)	(29,002)	(28,147)	(28,000)	(120,666)	(120,666)	(19,975)	(20,843)	(21,442)	(24,587)	(86,846)	58,278	244,779	524,714	635,823	834,215
Interest Income	1,873	897	646	172	-	1,715	-	-	-	-	-	-	-	-	-	-	-
Total Other Income	-	897	646	172	-	1,715	-	-	-	-	-	-	-	-	-	-	-
Pre-tax Income	(110,218)	(33,005)	(28,356)	(27,975)	(28,000)	(118,951)	(120,666)	(19,975)	(20,843)	(21,442)	(24,587)	(86,846)	58,278	244,779	524,714	635,823	834,215
Warrant deemed dividend	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Preferred stock deemed dividend	6,659	-	-	-	-	-	-	(1,997)	(2,084)	(2,144)	(2,459)	(8,685)	8,742	61,195	157,414	197,105	266,949
Taxes on income	-	-	-	-	-	-	-	10%	10%	10%	10%	10%	15%	25%	30%	31%	32%
Tax Rate	-	-	-	-	-	-	-	10%	10%	10%	10%	10%	15%	25%	30%	31%	32%
GAAP Net Income (Loss)	116,877	(33,005)	(28,356)	(27,975)	(28,000)	(117,336)	(120,666)	(17,977)	(18,759)	(19,297)	(22,128)	(78,162)	49,536	183,584	367,300	438,718	567,266
Total comprehensive loss	116,877	(33,005)	(28,356)	(27,975)	(28,000)	(117,336)	(120,666)	(17,977)	(18,759)	(19,297)	(22,128)	(78,162)	49,536	183,584	367,300	438,718	567,266
GAAP-EPS	3.27	(0.52)	(2.68)	(1.83)	(1.83)	(4.49)	(0.91)	(0.12)	(0.12)	(0.13)	(0.15)	(0.52)	0.33	1.21	2.41	2.87	3.69
GAAP-EPS (Dil)	3.27	(0.22)	(0.95)	(0.70)	(0.09)	(4.49)	(0.39)	(0.06)	(0.06)	(0.06)	(0.07)	(0.25)	0.16	0.59	1.17	1.40	1.80
Wgtd Avg Shrs (Bas) - '000s	35,739	63,353	10,587	15,327	15,342	26,152	132,813	150,450	150,601	150,752	150,902	150,676	151,280	151,886	152,494	153,105	153,719
Wgtd Avg Shrs (Dil) - '000s	35,739	150,000	30,000	40,000	307,000	26,152	307,768	308,538	308,847	309,155	309,465	309,001	310,239	311,482	312,730	313,982	315,240

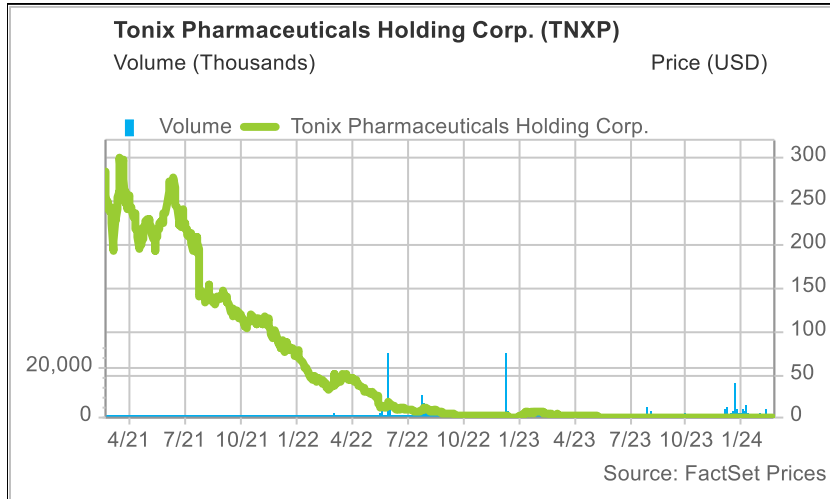
Source: Dawson James estimates.

Companies mentioned in this report:

Tonix Pharmaceuticals Holding Corp.

Important Disclosures:

Price Chart:



Price target and ratings changes over the past three years:

Initiated – Buy – February 28, 2024 – Price Target \$3.0

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- 1) **Buy:** The analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** The analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** The analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services.

Current as of 27-Feb-24

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	20	57.14%	4	11.43%
Market Perform (Neutral)	15	42.86%	2	5.71%
Market Underperform (Sell)	0	0%	0	0.00%
Total	35	100%	6	17.14%

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