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COMPANY NOTE | EQUITY RESEARCH | June 16, 2023

Healthcare: Biotechnology **Company Update**

Clene, Inc. | CLNN - $1.05 - NSQ | *Buy*

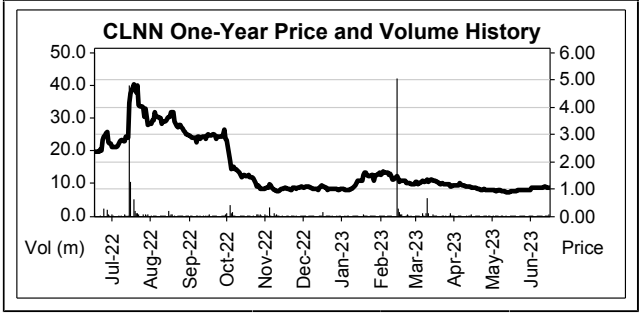
Stock Data	
52-Week Low - High	$0.85 - $5.13
Shares Out. (mil)	78.39
Mkt. Cap.(mil)	$82.31
3-Mo. Avg. Vol.	142,459
12-Mo.Price Target	$10.00
Cash (mil)	$18.4
Tot. Debt (mil)	$26.4

Rev ($M)

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	0.0A	0.1A	-
2Q	0.0A	0.1E	-
3Q	0.2A	0.1E	-
4Q	0.1A	0.1E	-
YEAR	0.3A	0.4E	30.6E

EPS $

Yr Dec	—2022—	—2023E—	—2024E—
		Curr	Curr
1Q	(0.21)A	(0.15)A	-
2Q	(0.07)A	(0.14)E	-
3Q	(0.17)A	(0.13)E	-
4Q	(0.01)A	(0.13)E	-
YEAR	(0.46)A	(0.56)E	(0.27)E



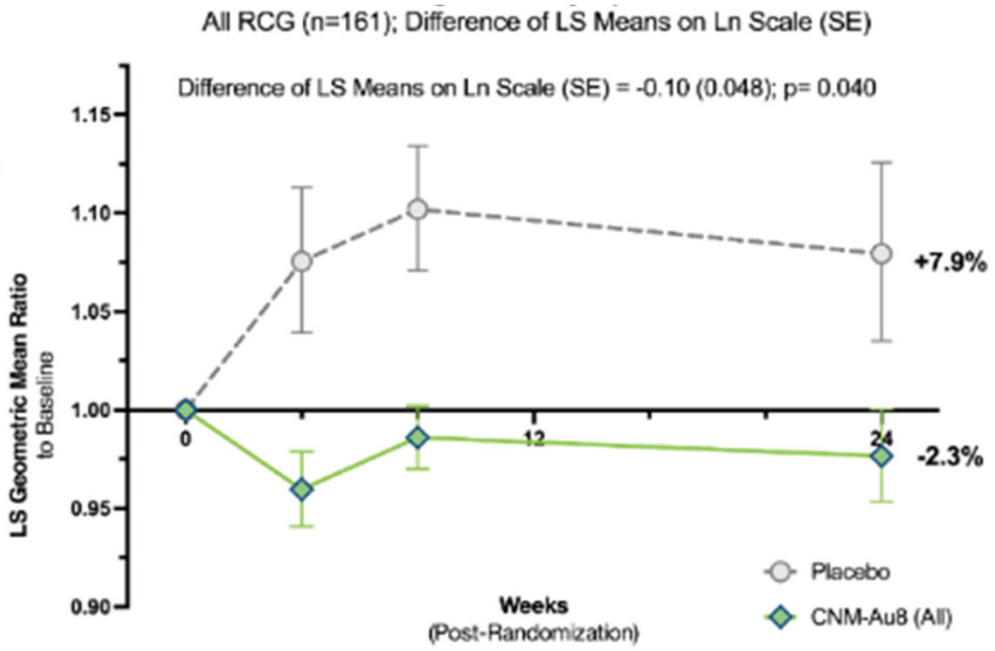
CLNN: Highly Encouraging Plasma NfL Biomarker Results for CNM-Au8 in HEALEY ALS

New results show a statistically significant reduction of plasma NfL, a key biomarker of neurodegeneration, at 24 weeks for CNM-Au8 versus placebo. Neurons release NfL following axonal injury, and the biomarker is particularly predictive of clinical decline and survival in ALS. NfL is also highly relevant to CNM-Au8's clinical prospects, given Biogen's (BIIB-NC) recent FDA approval for ALS drug Qalsody, which although it missed its primary, secondary, and exploratory endpoints, was essentially approved on strong NfL data after a 9-0 AdComm vote in its favor.

- **Reasons for optimism.** In the double-blind portion of the HEALEY ALS trial, new results show a statistically significant reduction of plasma neurofilament light chain (NfL) levels, a key biomarker of neurodegeneration, at 24 weeks for CNM-Au8 versus placebo. NfL is a relevant ALS biomarker, as neurons release it following axonal injury, and the biomarker is particularly predictive of clinical decline and survival in ALS. NfL is also highly relevant to the prospects for CLNN's clinical program, given Biogen's (BIIB-NC) recent FDA approval for ALS drug Qalsody, which although it missed its primary, secondary, and exploratory endpoints, was essentially approved on the NfL data after a 9-0 AdComm vote in its favor. AdComm panelists voted unanimously that Qalsody's demonstrated reduction in plasma NfL was “reasonably likely” to predict clinical benefit in ALS. BIIB did have a much greater difference in NfL levels between drug and placebo groups (i.e., 80%; 60% decrease for Qalsody versus 20% for placebo) than did CLNN (10% difference), but the trial was conducted in patients with less severe ALS on average, given that patients were selected based on the presence of mutations in superoxide dismutase 1 (SOD1). SOD1 is a protective antioxidant enzyme that was the first gene in which mutations were found to be causative for ALS. By contrast, CLNN took all comers and as such their trial enrolled both symptomatic and nonsymptomatic ALS patients. Qalsody is also intrathecally injected (Q28D maintenance dosing after three loading doses given at 14D intervals) versus CNM-Au8 being a far simpler to administer oral drug with a highly favorable safety and tolerability profile. CLNN also saw its survival and clinical worsening benefits during the randomized portion of its trials, whereas BIIB and Amylyx (AMLX-NC) saw these benefits during the open-label trial extensions. In our view, CLNN will likely put forth a strong argument for FDA approval based on data from existing CNM-Au8 trials and recent precedent set by BIIB, but the FDA could request a Phase 3 program if it is not compelled by the magnitude of the NfL differences versus what BIIB reported. NfL clearly appears to be predictive of clinical efficacy, but CLNN will still plan for a global Phase 3 ALS trial while preparing a complete clinical data package for a 3Q23 FDA regulatory discussion. *(text continued on page 2)*

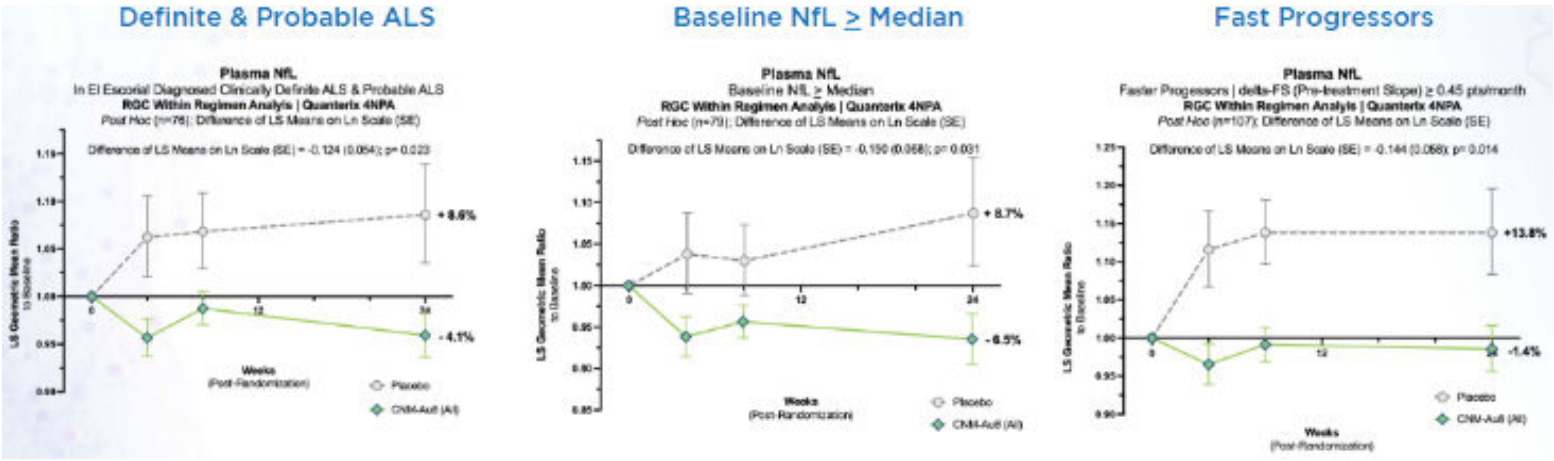
- **The 24-week NfL biomarker data.** The plasma NfL biomarker data are from 161 patients taking CNM-Au8 at either 30mg or 60mg daily or placebo (see figures on the following page). At 24 weeks, CNM-Au8 reduced plasma NfL levels versus placebo (LS means on a Ln scale for CNM-Au8 was -0.024 (SE: 0.024), for placebo was +0.076 (SE: 0.042)), and thus the difference was -0.100 (SE: 0.048), with a p=0.040. The CNM-Au8 benefit was even greater when conducting *post hoc* sensitivity analyses of enrollees at a relatively high risk for disease progression. For relatively fast progressors (n=107), defined as having a pre-treatment ALSFRS-R slope of $\geq$0.45 points/month, the difference of LS Means on a Ln Scale (SE) was -0.144 (0.058), with a p=0.014. For those with a definite or probable ALS diagnosis as per El Escorial criteria (n=125), the difference of LS Means on a Ln Scale (SE) was -0.124 (0.054), with a p=0.023. For those with higher mortality risk (n=79), defined as having a pre-treatment plasma NfL $\geq$ median, the difference of LS Means on a Ln Scale (SE) was -0.150 (0.068), with a p=0.031. CLNN is awaiting results for serum, which was specified as the primary blood matrix for analysis, to ascertain concordance between the two, and will report on other biomarker and long-term survival data from HEALEY later in 2023, but we note that BIIB was approved based upon plasma NfL results, which is encouraging for CLNN.

Plasma NfL Difference – CNM-Au8 Versus Placebo



Source: Clene, Inc. corporate presentation June 15, 2023

Consistent Plasma NfL Effects in Relatively High Risk ALS Patients



Source: Clene, Inc. corporate presentation June 15, 2023

VALUATION

Our 12-month price target of $10 is based on a DCF analysis using a 35% discount rate that is applied to all cash flows and the terminal value, which is based on a 4x multiple of our projected 2031 operating income of $1.2 billion.

Factors that could impede the achievement of our price target include, but are not limited to: (1) failure and/or setbacks of pipeline candidates in clinical trials; (2) failure of pipeline candidates to gain regulatory approval; and (3) smaller than projected commercial opportunity due to changes in market size, competitive landscape, and product pricing and reimbursement.

RISKS

- **Clinical risk.** CLNN's clinical staged products could fail to deliver statistically significant results in late-stage clinical trials, substantially reducing the value of CLNN's product candidates and therefore our target price.
- **Regulatory risk.** Even if successful in the clinic, CLNN's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce CLNN's value and therefore our target price.
- **Financing risk.** CLNN will need additional capital to fund its operations, and such financing may not occur, or it could be substantially dilutive to existing investors.
- **Competitive risk.** For any future approved CLNN products, they may not be well adopted in a competitive marketplace, which would adversely affect CLNN's value and therefore our target price.
- **High stock price volatility.** This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

Clene is a clinical-stage biopharmaceutical company focused on revolutionizing the treatment of neurodegenerative disease by targeting energetic failure, an underlying cause of many neurological diseases. The company is based in Salt Lake City, Utah, with R&D and manufacturing operations in Maryland. For more information, please visit www.clene.com.

Clene, Inc.
Income Statement
Fiscal Year ends December
(in $000, except per share items)

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	2020A	2021A	1Q22	2Q22	3Q22	4Q22	2022A	1Q23A	2Q23E	3Q23E	4Q23E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E	2031E
Product sales (ALS sales, RRMS royalties)	206	723	30	35	174	234	473	107	105	105	105	422	30,628	125,936	260,858	413,027	626,685	879,045	1,175,378	1,363,886
Total Revenue	**206**	**723**	**30**	**35**	**174**	**234**	**473**	**107**	**105**	**105**	**105**	**422**	**30,628**	**125,936**	**260,858**	**413,027**	**626,685**	**879,045**	**1,175,378**	**1,363,886**
Cost of revenue	65	289	-	-	19	7	26	5	11	11	11	37	3,063	12,594	18,260	20,651	31,334	43,952	58,769	68,194
Gross Profit	**141**	**434**	30	35	155	227	**447**	102	95	95	95	**386**	**27,565**	**113,343**	**242,598**	**392,376**	**595,351**	**835,092**	**1,116,609**	**1,295,692**
R&D	15,204	28,416	8,580	9,166	6,403	7,771	31,920	7,395	6,951	6,534	6,142	27,023	28,374	29,793	31,282	32,846	34,489	36,213	38,024	39,925
SG&A	5,151	21,996	4,786	4,464	3,557	4,129	16,936	3,439	3,473	3,508	3,543	13,964	20,946	26,182	28,800	30,240	31,752	33,340	35,007	36,757
Total Operating Expenses	**20,355**	**50,412**	**13,366**	**13,630**	**9,960**	**11,900**	**48,856**	**10,834**	**10,425**	**10,042**	**9,685**	**40,986**	**49,319**	**55,974**	**60,082**	**63,086**	**66,241**	**69,553**	**73,030**	**76,682**
Operating income	**(20,214)**	**(49,978)**	**(13,336)**	**(13,595)**	**(9,805)**	**(11,673)**	**(48,409)**	**(10,732)**	**(10,330)**	**(9,948)**	**(9,591)**	**(40,601)**	**(21,754)**	**57,368**	**182,516**	**329,289**	**529,110**	**765,540**	**1,043,579**	**1,219,010**
Interest expense	(950)	(870)	(782)	(751)	(857)	(906)	(3,296)	(1,066)	(900)	(765)	(650)	(3,381)	(2,029)	(609)						
Gain on extinguishment of notes payable		648					-	-				-								
Gain on termination of lease	51		420				420	-				-	-	-	-					
Change in fair value of preferred stock warrant liability	(14,615)						-	-				-								
Change in fair value of common stock warrant liability		983	(18)	20	149	18	169	-				-								
Change in fair value of derivative liability	29						-	-				-								
Change in fair value of Clene Nanomedicine contingent earn-out	12,659	33,953	(57)	8,310	(1,591)	9,174	15,836	(55)				(55)								
Change in fair value of Initial Shareholders contingent earn-out	1,465	3,589	(12)	1,066	(205)	1,177	2,026	(7)				(7)								
Australia research and development credit	3,210	1,519	299	356	1,346	1,078	3,079	314				314								
Loss on extinguishment of convertible notes	(540)						-	-				-								
Foreign currency translation adjustments	284	(92)		(147)	(6)	123	(30)	4				4								
Other income, net	34	(12)	132	60	(13)	78	257	(210)				(210)	-	-	-	-	-	-	-	-
Net income (pretax)	**(18,587)**	**(10,260)**	**(13,354)**	**(4,681)**	**(10,982)**	**(931)**	**(29,948)**	**(11,752)**	**(11,230)**	**(10,713)**	**(10,241)**	**(43,936)**	**(23,783)**	**56,760**	**182,516**	**329,289**	**529,110**	**765,540**	**1,043,579**	**1,219,010**
Income tax expense (benefit)	406	(428)					-					-				69,151	111,113	160,763	219,152	255,992
Net income	**(18,993)**	**(9,832)**	**(13,354)**	**(4,681)**	**(10,982)**	**(931)**	**(29,948)**	**(11,752)**	**(11,230)**	**(10,713)**	**(10,241)**	**(43,936)**	**(23,783)**	**56,760**	**182,516**	**260,139**	**417,997**	**604,776**	**824,427**	**963,018**
EPS basic	**(1.10)**	**(0.16)**	**(0.21)**	**(0.07)**	**(0.17)**	**(0.01)**	**(0.46)**	**(0.15)**	**(0.14)**	**(0.13)**	**(0.13)**	**(0.56)**	**(0.27)**	**0.58**	**1.76**	**2.39**	**3.66**	**5.04**	**6.54**	**7.28**
EPS diluted	**(1.10)**	**(0.16)**	**(0.21)**	**(0.07)**	**(0.17)**	**(0.01)**	**(0.46)**	**(0.15)**	**(0.14)**	**(0.13)**	**(0.13)**	**(0.56)**	**(0.27)**	**0.54**	**1.66**	**2.25**	**3.46**	**4.78**	**6.22**	**6.93**
Basic shares outstanding	17,300	61,558	62,853	63,335	63,509	71,122	65,205	76,050	78,407	79,975	81,575	79,002	89,732	98,706	103,641	108,823	114,264	119,977	125,976	132,275
Diluted shares outstanding	17,300	61,558	62,853	63,335	63,509	71,122	65,205	76,050	78,407	79,975	81,575	79,002	89,732	105,298	110,233	115,415	120,856	126,570	132,568	138,867

Source: SEC filings, company press releases, and ROTH MKM

Regulation Analyst Certification ("Reg AC"): The research analyst primarily responsible for the content of this report certifies the following under Reg AC: I hereby certify that all views expressed in this report accurately reflect my personal views about the subject company or companies and its or their securities. I also certify that no part of my compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in this report.

Disclosures:

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Shares of Clene, Inc. may be subject to the Securities and Exchange Commission's Penny Stock Rules, which may set forth sales practice requirements for certain low-priced securities.

Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

			IB Serv./Past 12 Mos. as of 06/15/23	
Rating	**Count**	**Percent**	**Count**	**Percent**
Buy [B]	**374**	**75.71**	**224**	**59.89**
Neutral [N]	**96**	**19.43**	**31**	**32.29**
Sell [S]	**3**	**0.61**	**0**	**0**
Under Review [UR]	**21**	**4.25**	**5**	**23.81**

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

Ratings System Definitions - ROTH MKM employs a rating system based on the following:

Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH MKM does not publish research or have an opinion about this security.