CIC

52 Wk. Lo/Hi

1.71 – 20.80

NLSP (lighter line) vs. Nasdaq Biotech price relative

Wednesday, 12 February 2025

Close Price	2.34
52 wk Range Low	1.71
52 wk Range High	20.80
MCAP (m)	$8.42
EV (m)	$9.15
Index: Public	NASDAQ
Financial YE	31-Dec
Currency	USD

Business Activity
Biotechnology & Medical Research

Key Metrics

Gross debt (m)	$1.63
Cash (m)	$0.90
Net Debt (Cash) (m)	$0.74
Net Operating Cash (m)	-$1.53
Revenue TTM(m)	$0.00
Net Income (loss) (m)	-$2.04

Key Ratios

(Net Cash) / Shareholder Equity %	7.94%

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NLS Pharmaceutics

Core Investment Case – Multiple DOXA Indications

Our CICs do not have valuations or forecasts. Financials are from Refinitiv et al.
NLS Pharmaceutics (NLSP:NasdaqCM) is a clinical-stage Swiss foreign issuer biotech advancing the Dual Orexin Receptor Agonist (DOXA) platform, a next-generation approach to treating neurological, neurodegenerative (NDD), and metabolic disorders. The DOXA platform is designed to restore orexin signaling and modulate neuroinflammatory pathways, offering a possible market leading approach to sleep-wake disorders, ALS, and other NDDs. The DOXA platform presents a high-value opportunity for breakthrough therapies, in CNS, immune dysregulation and metabolic medicine. Following shareholder approval and SEC sign off for the merger with KDST, NLSP will divest Mazindol and other assets, to focus on the DOXA pipeline.

- Orexin-based therapy for NDDs, ALS + metabolic dysfunction;
- Significant market opportunity possibly >US$ 200bn by 2030;
- IP portfolio - on-patent to end 2042 + rare disorder premium pricing;
- Platform technology – reduces gene therapy investment-risk;
- Divestment of legacy assets – proceeds go to NLSP shareholders.

USD (m)	MCAP	EV	ROIC %	RoE %	NCO	FCF
TTM	8.42	9.15	43%	23%	-1.53	-1.53

Multiples	EV/Revs	P/ S	Trail PE	BV/ S	P/ B	Current
TTM	NA	NA	-0.35x	-0.22x	-10.59x	0.15x

Summary Metrics (m)	2022A	2023A
Pre-Revenue	0.00	0.00
EBTIDA	-15.47	-11.80
EBIT	-15.48	-11.81
EBT	-16.50	-12.17
NI	-16.50	-12.17
EPS (Dil)	-0.84	-0.32
FCF	-13.88	-9.68
	NoSh	Fully diluted
NoSh (m)	3.60	5.66
NoSh (m) expected dilution (Exp D)		5.66
NoSh (m) full dilution (FD)		5.66

Key Metrics	$	adj.
MCAP (m)	8.4	8.4
Net Debt (Cash) (m)	0.7	0.7
EV (m)	9.2	9.2
52 Wk Hi	20.80	20.80
52 Wk Lo	1.71	1.71
Free Float	83.1%	89.2%
Effective Free Float	33.0%	N/A
M-Score	N/A	N/A

*Key Metrics FCF adj.	2022A	2023A
CPS ($)	-3.86	-1.71
CPS (Exp D) ($)		-1.71
CPS (FD) ($)		-1.71
P/CPS	-0.6x	-1.4x
P/CPS (Exp D)	NM	-1.4x
P/CPS (FD)	NM	-1.4x

Number of Shares Outstanding at date of note 3,597,641. Fully Diluted Shares 3,597,641. Source NLSP.

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Investment Case

NLS Pharmaceutics (NLSP:NasdaqCM) offers a compelling longer term investment opportunity addressing significant unmet needs. NLSP has long-life patents (out to 2042) and potential for a very significantly expanded market post its merger with KDST.TA. NLSP's DOXA platform targets multiple indications (multiple conditions it might treat e.g., obesity). The DOXA platform is built around dual orexin receptor agonists (OX1R & OX2R), coupled with cathepsin inhibition, enabling a multi-mechanism approach to neuroprotection, metabolic regulation, and sleep-wake control. The platform is currently advancing two lead compounds:

AEX-41: First-in-class dual orexin receptor agonist designed to enhance wakefulness, cognitive function, and metabolic regulation, targeting narcolepsy, metabolic disorders including diabetes, and ALS.

AEX-2: Next-generation orexin modulator with enhanced receptor selectivity, expanding potential applications to Parkinson's disease, Alzheimer's disease, and rare neuroinflammatory conditions.

IP Portfolio & Competitive Edge - First-in-class, non-sulfonamide-based dual orexin receptor agonists, improving safety and tolerability. Proprietary cathepsin inhibition technology, reducing neuroinflammation and protecting against protein aggregation—research suggests this is a major driver of neurodegeneration. **Patent protection** extending through at least 2042, ensuring long-term market exclusivity.

Market Opportunity in Neurology & Metabolic Disorders – An Expanding Pipeline Post Merger - **Neurodegenerative Diseases (NDDs)**: The global ALS market is expected to reach between $600m-$1bn by 2030. The total NDD therapy market exceeds $80bn. **Narcolepsy & Sleep-Wake Disorders:** The global market for narcolepsy and idiopathic hypersomnia (IH) is valued by one research house at $6.3bn by 2030. **Metabolic & Endocrine Disorders:** Orexin modulation has emerging applications in insulin resistance, obesity, and metabolic syndrome, presenting a $100bn+ market expansion opportunity.
Premium Pricing: Rare disease therapeutics command premium pricing, driven by orphan drug incentives, providing an environment where NLSP could achieve very attractive margins. There is limited competition for NLSP+KDST.TA combined IP and there are high barriers to entry for would-be competitors.

Catalysts

1. Merger approval from SEC. **2.** CVR divestment of legacy assets (NLSP shareholders only). **3.** Phase 1/2 trial for AEX-41 (2025) for NDD + metabolic regulation. **4.** Preclinical expansion of AEX-2, Parkinson's, Alzheimer's, and rare neuroinflammatories (2025/26). **5.** Potential licensing + collaboration deals with big pharma as interest in orexin-based therapies grows. **6.** Regulatory engagement for ODD in ALS + neuroinflammatory conditions.

Operational Strategy

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OX1R is selectively activated by orexin-A and plays a key role in regulating stress responses via the amygdala and hypothalamus. It modulates reward-seeking behaviours via the dopamine system, making it relevant for addiction therapy. It controls appetite and metabolism, influencing feeding behaviours and body weight regulation.

OX2R is activated by both orexin-A and orexin-B and is primarily responsible for wakefulness and arousal. Essential for sleep-wake stability—OX2R activation prevents REM sleep and so excessive daytime sleepiness. Neuroprotective functions—OX2R activation enhances neuronal survival and plasticity, making it a target for ALS, Parkinson's, and Alzheimer's disease therapies. Regulation of energy metabolism—OX2R is involved in glucose homeostasis and insulin sensitivity, suggesting a role in diabetes and other metabolic disorders.

NLSP's two innovative compounds, AEX-41 and AEX-2, are part of its DOXA platform. Both these first-in-class, non-sulfonamide DOXAs (AEX-41 and 2) are designed to target both the receptors orexin-1 (OX1R – anxiety, addiction, stress, relaxation) and orexin-2 (OX2R – sleep wake stability, neuroprotectivity, insulin sensitivity and energy metabolism) while concurrently inhibiting cathepsins (lysosomal proteases playing a key role in protein turnover, immune regulation, metabolic balance and neurodegeneration and cancer cell spreading). In metabolic disorders regulating cathepsin activity could improve insulin sensitivity and fat metabolism, making DOXA a potential therapy for Type 2 Diabetes (T2D) and obesity.

In preclinical studies conducted at the Centre for Neuroscience Research of Lyon, AEX-41 demonstrated a significant increase in wakefulness and a reduction in REM sleep duration in orexin knockout mice. These effects are crucial for managing the core symptoms of narcolepsy. The efficacy of AEX-41 was comparable to existing selective OX2R agonists, highlighting its potential as a versatile alternative for broader therapeutic applications.

Scalable Path from Clinical Trials to Commercialization - NLSP has designed a focused operational strategy centred around clinical execution, scalable manufacturing and market entry planning via big pharma partners to maximise DOXA's potential.

Regulatory & Clinical Execution Strategy – NLSP is organising to accelerate approval times and via its merger with KDST.TA, achieve significantly expand market reach. The pathway to achieve this acceleration is as follows: Gain SEC approval for the reversal of KDST.TA into NLSP followed by a programmed phase 1/2 trial for AEX-41 & AEX-2, with first in-human trials (2025) for AEX-41 in ALS and metabolic dysfunction. This is to be combined with targeted biomarker-driven endpoints to validate neuroprotection and orexin pathway activation. NLSP intends to follow up with expanded trials in 2026 to evaluate cognitive benefits in Parkinson's disease and Alzheimer's disease.

Upon success, NLSP will run an orphan drug and fast track regulatory strategy that targets FDA Orphan Drug Designation (ODD) for ALS, to win 7 years of market exclusivity, post-approval, and potential fast track designation based on preclinical neuroinflammatory data, accelerating review timelines.

Cost Optimization, Pricing and Commercialization Strategy - NLSP is using synthetic chemistry to cut production costs, the trick is to maintain high receptor sensitivity. Pricing models are to be designed to align with reimbursement expectations, ensuring adoption rather than necessarily arriving with premium pricing and no takers. The merger may lead to a refinement of this approach. Whatever the outcome, we assess that orexin-targeting drugs are a major area of interest for mid and large cap pharma companies such as Jazz Pharmaceuticals (JAZZ:NasdaqGS), Takeda (TAK:NYSE), and Axsome (AXSM:NasdaqGM).

Management Team

➢ Chairman, Ronald Hafner.

Infosys acquired Lodestone Management Consultants for approximately US$ 350m in 2012, according to The Economic Times (India).

Ronald is Chairman of NLS Pharmaceutics, since August 2015. He is also currently a partner at Deloitte Consulting, Switzerland and chairman of UK based investment vehicle Magnetic Rock. Ronald has also served as the CEO of Infosys Consulting, following its acquisition of his company Lodestone Management Consultants, a global business specialising in business process and SAP technologies. Ronald was responsible for Lodestone's global operations. Mr. Hafner has also served as an independent director of the Pingar Group Ltd., a private company developing AI software solutions for productivity and compliance. Mr. Hafner holds an MBA and a master's degree in economics from the University of Basel/Switzerland.

➢ Co-founder & CEO, Alexander Zwyer, MBA.

Alex Zwyer's luxury food start-up company attracted several Michelin-starred Chef clients in Switzerland and France as well as luxury hotels before he sold it in 2016 to an undisclosed private equity firm for an undisclosed sum.

The company continues to operate in the luxury food (and now cosmetics) segments.

Alex co-founded and has served as CEO of NLS Pharmaceutics since its inception in August 2015. Alex has over 25 years of international entrepreneurial business experience. He has spent over 10 years in C-suite healthcare biotech roles including with Viforpharma (SWX:VIFN), formerly Vifor Inc., where, as COO he led the company's global regulatory affairs, medical affairs, sales and marketing and business development teams. Prior to NLS, Mr. Zwyer founded and sold a high-end luxury food sector company. Alex is a natural linguist (fluency in 7 languages) and holds a BBA in business administration from Oekral, Zurich, Switzerland, an executive MBA from GSBA/Lorange Institute of Business, Zurich, Switzerland and an MBA from University at Albany SUNY, USA.

➢ Co-founder & CSO, Dr. Eric Konofal, MD., PhD.

Dr Konofal has been cited and contributed to numerous (at least 70) contemporaneous peer reviewed papers in the field of psychotropic drugs, often related to sleep disorders, iron deficiency in relation to ADHD and in other related CNS research.

Dr Konofal has conducted extensive research on Ritalin (Methylphenidate) marketed by Novartis (NVS:NYSE), formerly CIBA, to treat ADHD and narcolepsy. Ritalin was discovered in 1944 by Leandro Panizzon, whilst at CIBA.

Dr. Konofal is a co-founder and Chief Scientific Officer (CSO) of NLS Pharmaceutics. He discovered the pharmacological profile of mazindol and its orexin-2 receptor binding properties, leading to NLSP's DOXA platform and so the KDST+NLSP merger. Eric is a primary clinical and international scientific researcher. His research has focused on brain and iron-dopamine interactions in subjects with neurological sleep disorders (RLS, PLMS), and ADHD. Eric has been involved in the discovery and development of several drugs including Mazindol, Nolazol and Quilience. Dr Konofal is also a senior medical consultant for the Pediatric Sleep Disorders Center at Robert-Debre University of Paris (APHP), where he previously served as Principal Clinical Investigator in the Clinical Pharmacology & Pharmacogenetic Department. Additionally, Dr. Konofal served as a consultant at the sleep disorder center of Pitié-Salpêtrière University Hospital Group (APHP), specializing in ADHD, RLS, PLMS (RLS and PLMS are sleep related movement disorders and CDH (a type of chronic migraine disorder).

Risks

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Funding risk – Developing cell and gene therapies requires substantial capital investment. While NLSP holds 12 months of cash reserves, future funding needs could dilute shareholder value. The Company has incurred significant losses in prior periods and expects more losses over the coming years as it advances its development and commercial programs. To date, the Company has generated no revenue and is unlikely to do so in the near future. Failure to raise sufficient funds could raise doubts over its ability to remain a going concern. As a clinical-stage company, NLSP relies on external funding for its operations and clinical programs. Delays in raising capital will impact progress.

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Whilst orexin-targeting therapies remain an emerging field, preclinical evidence and targeted orphan drug strategies improve the probability of success.

Regulatory risk – Novel platforms face rigorous regulatory scrutiny, with potential delays in trial approvals or commercial licensing. The regulatory approvals process for new therapeutic products is time consuming, expensive, and uncertain. The company must provide regulatory authorities with preclinical and clinical data demonstrating that its therapies are safe and effective before they can be approved for commercial sale. Any preclinical or clinical test may fail to produce results that are satisfactory to regulators. Orexin-targeting therapies remain an emerging field.

Whilst new CNS therapies require physician education and reimbursement approvals. Building key opinion leader (KOL) networks and early payer engagement strategies is a mitigation.

Competition risk - The cell and gene therapy space is rapidly evolving, with major competitors. The biotechnology and pharmaceutical industry is highly competitive. There are many companies that are seeking to develop products and therapies for the treatment of the same range of diseases as the company. There are competitors with greater financial resources and more experience in advancing the drugs through various stages of regulatory approvals and then to commercialization. New CNS therapies require physician education and reimbursement approvals.

Intellectual Property risk – Early-stage programs carry inherent risks, including the possibility of unfavorable preclinical or clinical outcomes. Manufacturing challenges abound, scaling production of therapies remains a technical challenge, requiring continuous investment and innovation. The Company is, in the near term, dependent on its proprietary technology platform, therefore its near-term success depends on its ability to protect its IP. This is likely to include commercially key patents related to the production method of the Company's proprietary platforms. Failure to be able to protect its IP in practice, could have an adverse impact on the business operations.

Personnel - Small and mid-sized companies are more dependent on their C-suite/executive management teams than large / mega-cap global companies. The loss of key personnel can have a disproportionate impact on valuation and investor perception cf. similar events at larger, more mature (often ex-growth) companies.

Financial Metrics Historical

Financial Metrics Historical	2020	2021	2022	2023	TTM	2Q23	3Q23	4Q23	1Q24	2Q24
Capital & Debt										
Debt Ratio	841.5%	90.6%	64.6%	578.4%	876.6%	296.4%	64.6%	288.8%	578.4%	876.6%
Debt to Equity	-23.2%	0.0%	0.0%	-18.5%	-18.5%	-8.8%	0.0%	0.0%	-18.5%	-18.5%
Short Term Debt / Equity	-19.7%	0.0%	0.0%	-18.5%	-18.5%	-8.8%	0.0%	0.0%	-18.5%	-18.5%
Debt>1yr/Net Inv. Capital	-4.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Assets/Equity	-13.5%	1062.8%	282.8%	-20.9%	-12.9%	-50.9%	282.8%	-53.0%	-20.9%	-12.9%
SR Liquidity					TTM					
Quick	0.0x	2.4x	2.8x	0.2x	0.2x	0.6x	2.8x	0.6x	0.2x	0.2x
C&CE/ Current Liabs	0.0x	2.3x	2.7x	0.1x	0.1x	0.4x	2.7x	0.4x	0.1x	0.1x
NCO / Total Current Liabs	-0.1x	-6.2x	-4.1x	-1.2x	-0.2x	-2.2x	-1.8x	-1.9x	0.0x	-0.2x
TCA/ Avg. Daily Costs	0.0x	0.5x	0.6x	0.2x	0.6x	0.2x	1.6x	0.3x	220.8x	0.6x
Returns					TTM					
RoA	-236.2%	-207.2%	-177.8%	-659.1%	-171.0%	-419.9%	-84.7%	-335.3%	-0.2%	-170.6%
RoE	31.9%	-2202.5%	-502.8%	137.8%	22.0%	213.8%	-239.4%	177.6%	0.1%	22.0%
RoIC	32.8%	238.0%	273.2%	145.8%	25.4%	172.3%	119.9%	127.1%	0.1%	25.3%
CRoIC	10.4%	306.3%	244.9%	119.6%	18.9%	152.1%	109.6%	122.9%	0.0%	18.9%
RoCE	38.4%	-352.9%	-261.7%	194.4%	31.5%	642.3%	-114.8%	465.4%	0.1%	31.5%
GP/Total Assets	0.0%	-0.2%	-0.1%	-0.6%	-1.0%	-0.3%	-0.1%	-0.3%	-0.3%	-0.5%
Price					TTM					
PEx		-54.8x	-61.4x	-63.3x	-16.6x	-4.3x	-8.1x	-11.7x	-16.6x	
PEG		-147.0x	-1658.6x	102.2x	0.0x	0.0x	17.4x	37.7x	56.0x	
P/B		1207.3x	309.6x	-87.5x	-10.6x	-9.2x	19.0x	-20.8x	-8.6x	-10.6x
P/TBV		113.6x	109.5x	418.4x	82.2x	18.1x	6.7x	39.4x	41.1x	82.2x
P/NCA		113.6x	109.5x	418.4x	82.2x	18.1x	6.7x	39.4x	41.1x	82.2x
P/NCO		-43.8x	-73.2x	-79.8x	-64.0x	-4.9x	-10.0x	-12.2x	-31777.9x	-64.1x
P/FCF		-43.7x	-73.2x	-79.8x	-64.0x	-4.9x	-10.0x	-12.2x	-31777.9x	-64.1x
EV					TTM					
EV/GP		-54.8x	-65.1x	-65.6x	-15.6x	-4.2x	-7.9x	-11.6x	-17.4x	-51.1x
EV/EBITDA		-54.8x	-65.1x	-65.6x	-15.6x	-4.2x	-7.9x	-11.6x	-17.4x	-51.1x
EV/EBIT		-54.8x	-65.0x	-65.5x	-48.3x	-4.2x	-7.9x	-11.6x	-17996.1x	-48.4x
EV/FCF		-43.4x	-72.5x	-79.9x	-64.8x	-4.7x	-8.6x	-12.0x	-32086.2x	-64.9x
FCF					TTM					
EV/FCF		-4336.4%	-7253.0%	-7986.2%	-6478.8%	-472.1%	-860.8%	-1201.7%	-3208618%	-6488.9%
uFCF/EV		-2.3%	-249.8%	-1.2%	0.0%	0.0%	-11.4%	-8.4%	3.7%	-2.9%
lFCF/MCAP		-0.7%	0.1%	0.4%	0.0%	0.0%	-0.6%	0.0%	2.2%	-0.1%
Interest Cover					TTM					
EBIT/Ip		-174.1x	-153.5x	-81.3x	-8.9x	-946.4x	-74.1x	-58523.1x	0.0x	-23.6x
EBITDA/Ip		-173.9x	-153.4x	-81.3x	-27.4x	-945.8x	-74.0x	-58478.9x	-30.4x	-22.3x
(EBITDA-Capex)/Ip		-173.3x	-153.4x	-81.3x	-27.4x	-945.8x	-74.0x	-58478.9x	-30.4x	-22.3x
Dividends					TTM					
Div Payout %	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Div Yield %		0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Retention %	1040.0%	349.1%	352.8%	578.2%	3548.8%	582.7%	741.0%	864.5%	1543518%	3556.7%

Sources: ACF Equity Research; Refinitiv.

Notes [Intentionally Blank]

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Christopher Nicholson
Managing Director
Head of Research
ACF Equity Research Ltd

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