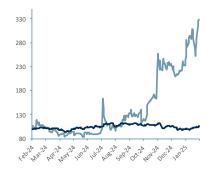
# CIC

# 52 Wk. Lo/Hi

430 - 1942



KDST (lighter line) vs. Nasdaq Biotech price relative

#### Monday, 10 February 2025

Close Price	1,886.00
52 wk Range Low	430.00
52 wk Range High	1,942.00
MCAP (m)	75.91
EV (m)	78.07
Index: Public	TLV
Financial YE	31-Dec
Currency	ILA
Business Activity	
Biotechnology &	
Medical Research	
Key Metrics	
Gross debt (m)	6.32
Cash (m)	4.16
Net Debt (Cash) (m)	2.17
Net Operating Cash (m)	-0.01
Revenue TTM(m)	0.00
NetIncome (loss) (m)	-0.01
Key Ratios	
(Net Cash) /	26.63%
Shareholder Equity %	
Healthcare Sector Research	
TLV Market Index	

### ACF Healthcare Team

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# Kadimastem Ltd.

### Core Investment Case – Potential T1 Diabetes Cure

*Our CICs do not have valuations or forecasts. Financials are from Refinitiv et al.* Kadimastem (KDST.TA:TASE) is an Israeli-based clinical-stage cell therapy company pioneering regenerative medicine for insulin dependent type 1 diabetes (T1D) (no more injections) and amyotrophic lateral sclerosis (ALS). KDST has a proprietary stem-cell differentiation platform for scalable therapies designed to replace lost or damaged cells. KDST's T1D IsletRx program aims to revolutionize insulin production for diabetes patients using off-the-shelf allogeneic encapsulated pancreatic islet cells with immune protection. AstroRx<sup>®</sup> targets neurodegenerative diseases (NDDs), particularly ALS. KDST.TA is merging with NLSP – a significant value inflection point.

- Revolutionizing T1D w/ IsletRx stem cell derived pancreatic islets;
- GMP cert. manufacturing (scalability), proprietary encapsulation;
- Pioneering ALS AstroRx<sup>®</sup> therapy targets astrocyte cells;
- Booming cell therapy market T1D therapy market US\$40bn;
- Upcoming catalysts in 2025 P2 for IsletRx, NLSP merger.

ILa (m)	MCAP	EV	ROIC %	RoE %	NCO	FCF
TTM	76	261	1.01%	0.16%	-0.01	-0.01
Multiples	EV/Revs	P/S	Trail PE	BV/S	Р/В	Current
TTM	828682x	774549x	-6.61x	-0.20x	-92.27x	0.33x

ACF EQUITY RESEARCH LIMITED CORE INVESTMENT CASE



Summary Metrics (m)	2022A	2023A
Pre-Revenue	0.00	0.00
EBTIDA	-20.69	-10.66
EBIT	-22.01	-11.04
EBT	-22.89	-12.21
NI	-22.72	-12.05
EPS (Dil)	-0.65	-0.28
FCFE	1.00	3.89
	NoSh	Fully diluted
NoSh (m)	4.19	7.05
NoSh (m) expected dilution (Exp D)		7.05
NoSh (m) full dilution (FD)		7.05
Key Metrics	ILA	adj.
MCAP (m)	75.9	75.9
Net Debt (Cash) (m)	2.2	2.2
EV (m)	78.1	78.1
52 Wk Hi	1,942.00	1,942.00
52 Wk Lo	430.00	430.00
Free Float	39.8%	64.2%
Effective Free Float	39.8%	64.2%
M-Score	N/A	N/A
*Key Metrics FCF adj.	2022A	2023A
CPS (\$)	-4.92	-1.58
CPS (Exp D) (\$)		-1.58
CPS (FD) (\$)		-1.58
P/CPS	-383.3x	-1196.8x
P/CPS (Exp D)	NM	-1196.8x
P/CPS (FD)	NM	-1196.8x

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### **Investment Case**

Kadimastem offers a compelling investment case with its innovative stem cell platform targeting major unmet needs in diabetes and ALS (Lou Gehrig's/Motor Neurone Disease). With promising clinical results, a robust R&D pipeline, and a clear focus on scaling its operations, the company is wellpositioned to capture significant value in the regenerative medicine market. Whilst the usual pre-revenue biotech investment risks exist, key milestones including the shareholder approved merger with NLSP (Nasdaq) provide potential catalysts for valuation crystallisation and a much expanded potential valuation for the combined entities and their IP protected technologies:

**IsletRx:** Addressing Insulin-Dependent Diabetes (T1D) - IsletRx leverages Kadimastem's stem cell technology to create insulin-producing beta cells encapsulated to avoid immune system rejection. This treatment aims to provide long-term glycemic control for diabetes patients without the need for continuous insulin injections.

AstroRx<sup>®</sup>: Advanced Therapy for ALS - AstroRx<sup>®</sup> is a cell therapy comprising healthy, functioning astrocytes derived from human embryonic stem cells (hESC), designed to slow disease progression for ALS patients. Phase 1/2a clinical trials indicated safety and tolerability, with preliminary efficacy results indicating slowed disease progression and neuroprotective effects.

**Market Opportunities:** Diabetes: A rapidly growing global market, projected to exceed \$22bn by 2030 (Grand View), a near doubling since 2019 estimates, driven by increasing prevalence of T1D and demand for treatments. ALS: A global therapy market valued at ~\$600M annually today, growing potentially to ~950m by 2030 (Data Bridge, Spherical Insights). There are no current cures for ALS. The merger with NLSP may expand these opportunities markedly because of the attributes of NSLP's DOXA platform.

**Proprietary Technology** -Kadimastem's stem cell differentiation technology is protected by multiple patents, enabling the production of functional cells to address various neurodegenerative and endocrine disorders. This platform positions the company as a potential leader in regenerative medicine.

**Collaborative and Strategic Partnerships** -Research collaborations with leading institutions, including Tel Aviv University and the Weizmann Institute of Science and strategic partnerships to expand manufacturing capacity and clinical trial support.

### **Catalysts**

**1**.SEC approval of the reverse merger with NLSP. **2**. Completion of P2a clinical trials for AstroRx<sup>®</sup> (2025). **3**. Preclinical progress and regulatory submission for IsletRx. **4**. Expansion of partnerships for manufacturing and distribution. **5**. Potential out-licensing deals to support commercialization.



### **Operational Strategy**

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GMP(Good Manufacturing Practices) facilities. GM practices are designed to ensure reliable and consistent manufacturing processes that are documented, meet regulatory compliance, impose effective training and regular inspections to ensure clean, uncontaminated and appropriately maintained facilities.

Kadimastem is evaluating biocompatible polymers that enhance implantation success rates and improve cell longevity post-transplant.

Kadimastem's encapsulation approach avoids immunosuppression, making it a more patient-friendly option—a major selling point for commercial adoption and a significant competitive advantage in respect of other beta cell therapies from providers such as Vertex (VXRT). **Operational Strategy** – Kadimastem focuses on diseases with high unmet needs and scalable commercial potential. KDST's strategy prioritizes advancing its clinical-stage AstroRx<sup>®</sup> program while accelerating the preclinical programme for IsletRx. The NLSP reverse merger will, in all likelihood, accelerate the business model, broaden its market reach and create a potentially unassailable technical moat for KDST. The Company's operational strategy is built on 3 core pillars: clinical execution, scalable manufacturing, and commercialization readiness (in part via its IP / licensing strategy).

**1. Clinical Execution & Regulatory Approach**: KDST is developing cell therapy pipelines whilst aligning its approach with global regulatory agencies (FDA, EMA, Israeli MOH).

AstroRx<sup>®</sup> P2 Initiation (2025): Kadimastem is preparing for multi-center P2 trials that will evaluate IsletRx's long-term insulin independence and immune evasion capabilities and biomarker defined endpoints, with the aim of accelerating regulatory approval via breakthrough therapy or orphan drug designations. Additional preclinical studies are underway to refine IsletRx's dosing regimen and optimize encapsulation performance for long-term implantation.

AstroRx<sup>®</sup> Expansion & ALS Market Penetration Strategy: KDST is seeking expanded access (2025) for AstroRx<sup>®</sup> by engaging with regulators to secure broader patient access ahead of pivotal AstroRx<sup>®</sup> trials. Given the high-cost burden of NDDs, KDST is developing an optimized treatment for scaled mass production ahead of P3 trials. The Company is using an adaptive clinical trial design to allow for real-time modifications based on biomarker readouts – the goal is to improve trial efficiency. KDST is also engaging with key opinion leaders (KOLs) to strengthen regulatory positioning and increase the probability of rapid clinical adoption post-approval.

**2. Manufacturing and Scalability** – Our research points to KDST cellular manufacturing excellence in a likely state-of-the-art GMP facility (quality and scalability), enabling end-to-end control of stem cell manufacturing, differentiation and encapsulation (delivers immune protected islet transplants, i.e., immunosuppression is not required) and so low batch variability – low variability is a significant competitive advantage in cell manufacture. The current facility in Israel can produce sufficient cell volumes annually to treat >2,000 patients. KDST plans to expand the volume capacity of the GMP facility. The Company is pursuing a collaborative ecosystem creating partnerships with academic institutions, healthcare providers, CDOs and other industry players, that should help optimise R&D and production costs and accelerate its innovation cycle.

**3. Commercialization & Market Access Plan** – licensing to major diabetes (e.g., Eli Lilly LLY, Novo Nordisk NVO, and Sanofi SNY) and NDD pharma companies in the US, with a concomitant direct market entry approach using a specialized sales force in the EU and Israel. Reimbursement and market access planning is ongoing in the US, EU and Israel along with physician and patient engagement to drive adoption. For ALS (AstroRx<sup>®</sup>) we expect a premium tier pricing model in developed markets, suggesting US\$250k per patient per annum.



### **Management Team**

### > Chairman & CEO, Ronen Tweto.



Ronen is Executive Charman and CEO of Kadimastem since Dec 2020. He has successfully established KDST as an emerging global leader in the cell therapy industry. Ronen brings over 20 years of biotech listed company value generation success on both Nasdaq and TASE. His experience includes executing multiple IPOs, secondary raises, M&A transactions and licensing and collaboration agreements. Prior to KDST, Ronen held a range of executive and C-suite roles including at XTL Biopharmaceuticals (

XTLB), Intercure, Bubbles Intergroup (BBLS.TA), Cellect Biotech (APOP) and MTS (MTSL). Formerly, he was Corporate Finance Director at LeadCom Integrated Solutions, a global company traded on London's AIM market, and a Manager at Ernst & Young. Ronen is a Certified Public Accountant (CPA) in Israel and holds a bachelor's degree in Business Administration and Accounting.

### > Co-Founder & CSO, Professor Michel Revel, MD., PhD.



Prof. Revel is Co-founder and Chief Scientific Officer (CSO) at KDST His research on interferon is renown. Interferons are implicated in Type 1 Diabetes and other autoimmune conditions. Prof Revel is also Professor Emeritus of Molecular Genetics at the Weizmann Institute of Science. His work on the mechanism and the isolation of the human Interferon-beta gene, have led to the development of blockbuster Interferon-beta therapy for MS, Rebif<sup>®</sup>. More recently Prof Revel's hESC work produced transplantable nerve

myelinating cells that regenerated the myelin coating in animals. These studies contributed to the development of insulin-producing pancreatic beta cells and nerve myelinating cells. Prof Revel also has a reputation as a biotechnology ethicist, is a recipient of the Israel Prize for medical research, the EMET Prize for biotechnology, and is a member of the Israel Academy of Science and Humanities. Prof Revel's work on interferon has generated numerous peer reviewed papers and citations.

### > Director of Medical Affairs, Ariel Revel, MD..



Prof. Ariel Revel, MD, is a professor of medicine at Tel Aviv University and a Visiting Professor at Oxford University in the UK and Stanford University in California. He is a respected author and figure on the medical landscape. At Kadimastem, Prof Revel is responsible for advocating the surgical and medical aspects of islet transplantation for patients with diabetes; promoting cell therapy as the future of medicine to the medical practitioner community as a route to improve and potentially cure neurodegenerative

diseases such as ALS and to present the case to the general public and potential inventors for the potential of human embryonic stem cells to cure Diabetes, Glaucoma and Traumatic Spinal Cord Injuries.

Rebif® is an injectable multiple sclerosis (MS) therapy marketed by Merck (MRK:NYSE) reaching peak revenues of ~US\$ 2bn in 2008 (fortunebusinessinsights.com. pharmphorum.com)



### Risks

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The financial metrics in this core investment case are based solely upon financial report and accounts and publicly available data from platforms such as Refinitiv, they do not contain our analysis, forecasts or valuation work, these will be found in our forthcoming initiation note and subsequent research updates et al. **Funding risk** – Developing cell and gene therapies requires substantial capital investment. 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. The Company would need access to capital to fund these losses. To date, the Company has generated no revenue and is unlikely to do so in the near future. The Company requires significant capital to progress its pipeline and expand manufacturing capacity. Delays in raising funds may impact clinical timelines.

**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. Success depends on both obtaining and then maintaining regulatory approvals, which can be uncertain and time-consuming.

**Competition risk** - The cell and gene therapy space is rapidly evolving, with major competitors that are better cash resourced and more experienced at advancing therapies through regulation on to commercialization, potentially capturing greater market share. 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.

**Intellectual Property risk** – Early-stage programs carry inherent risks, including the possibility of unfavorable preclinical or clinical outcomes. Manufacturing challenges abound, scaling production of allogeneic 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, including 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 including scientific leadership can have a disproportionate impact on valuation and investor perception cf. similar events at larger, more mature (often exgrowth) companies.



Financial	Metrics	Historical	
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Financial Metrics Historical	2020	2021	2022	2023	TTM	2Q23	3Q23	4Q23	1Q24	2Q24
Capital & Debt										
Debt Ratio	174.7%	43.7%	97.4%	152.1%	251.5%	98.2%	152.1%	152.1%	251.5%	251.5%
Debt to Equity	-160.8%	38.7%	2187.4%	-145.0%	-90.4%	3648.5%	-145.0%	-145.0%	-90.4%	-90.4%
Short Term Debt / Equity	-146.5%	36.2%	1708.6%	-125.9%	-90.4%	3289.9%	-125.9%	-125.9%	-90.4%	-90.4%
LT Debt /Equity	-14.3%	2.5%	478.8%	-19.1%	0.0%	358.6%	-19.1%	-19.1%	0.0%	0.0%
Debt <=1yr/ Gross Debt	91.1%	93.6%	78.1%	86.8%	100.0%	90.2%	86.8%	86.8%	100.0%	100.0%
Debt>1yr /Gross Debt	8.9%	6.4%	21.9%	13.2%	0.0%	9.8%	13.2%	13.2%	0.0%	0.0%
Debt>1yr/Net Inv. Capital	-217.5%	-19.4%	146.6%	-38.1%	0.0%	28.3%	-38.1%	-38.1%	0.0%	0.0%
Assets/Equity	-133.8%	177.8%	3831.0%	-191.9%	-66.0%	5659.2%	-191.9%	-191.9%	-66.0%	-66.0%
NCO/Gross Debt	-168.4%	-362.2%	-280.4%	-175.3%	-0.1%	-0.1%	0.0%	0.0%	0.0%	0.0%
SR Liquidity					TTM					
Quick	0.4x	2.1x	0.7x	0.7x	0.3x	0.6x	0.7x	0.7x	0.3x	0.3x
C&CE/ Current Liabs	0.3x	2.1x	0.6x	0.5x	0.2x	0.5x	0.5x	0.5x	0.2x	0.2x
NCO / Total Current Liabs	-1.3x	-1.9x	-1.9x	-1.3x	0.0x	0.0x	0.0x	0.0x	0.0x	0.0x
TCA/ Avg. Daily Costs	0.4x	1.2x	0.4x	0.6x	857.9x	1.3x	2943.8x	2721.5x	8483.6x	8483.6x
Returns					TTM					
RoA	-201.2%	-96.1%	-181.9%	-144.0%	-0.2%	0.0%	0.0%	0.0%	0.0%	0.0%
RoE	269.3%	-170.8%	-6968.7%	276.3%	0.1%	-2.0%	0.1%	0.1%	0.0%	0.0%
RoIC	3773.1%	1215.2%	-2051.0%	513.0%	0.3%	-0.2%	0.1%	0.1%	0.1%	0.1%
CRoIC	4140.9%	1124.9%	-1937.7%	507.1%	0.2%	-0.2%	0.1%	0.1%	0.1%	0.1%
RoCE	307.3%	-150.3%	-1125.8%	-8692.1%	0.1%	-0.4%	-1.8%	-1.8%	0.0%	0.0%
GP/Total Assets	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
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%	0.0%
Retention %	860.7%	811.5%	1037.1%	2055.5%	25953x	70319x	96155x	96155x	110450x	110450x

Sources: Refinitiv



## Notes [Intentionally Blank]



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Christopher Nicholson Managing Director Head of Research ACF Equity Research Ltd

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