

Q4 2019 Update

April 25, 2020



Announced on high potential licensing agreement; Successful preclinical results can positioning Kadimastem within the Diabetes Cell Therapy market

Primary Exchange:
TASE

Ticker: TLV:KDST

Sector: Healthcare

Industry:
Pharmaceuticals

Data as at April 23rd 2020

(Source: TASE)

Closing price: NIS 0.35

Market cap: NIS 43M

of shares: 124.2M

Stock performance (12 mos.): -7%

Daily-trading-vol. (3 mos.): 112

Stock target price:
NIS 0.96

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Company Overview

Kadimastem Ltd. (hereinafter "Kadimastem" or "the company") is a clinical stage biopharmaceutical company that specializes in developing different types of human body cells (known as differentiated cells) – such as neural cells (e.g. oligodendrocytes and astrocytes) and insulin secreting beta cells, derived from human embryonic stem cells. The company has its technological platform and two current stem cell based therapies in research phases – AstroRx (consists of astrocytes, a type of brain cell) and Encapsulin (insulin secreting beta cells) for treating amyotrophic lateral sclerosis (ALS) and diabetes respectively.

Highlights & Analysis

On March 31st Kadimastem released its 2019 annual and Q4 report with the following recent highlights:

- **AstroRx®:** The first of 3 cohorts participating in the Phase 1/2a Kadimastem clinical trial for the treatment of ALS showed promising results 6 months after treatment using the gold standard ALSFRS function test.
- The spread of the corona virus affects the conduct of clinical trials in Israel and around the world. This is especially true for ALS patients who's lung function is at risk.
- In March 2020, Kadimastem announced that it is in advanced negotiations with Hadasit, the technology transfer office of the Hadassah University Hospitals from which Kadimastem's AstroRx was derived, to extend Kadimastem's license to allow for the development of additional cellular products that will treat central nervous system diseases and potentially diseases from other categories. **These advanced negotiations are testimony to the great potential of Kadimastem's technology not only as a solution for ALS but as a platform to treat multiple diseases through cell therapy.**
- On April 6, 2020, the Company received approval from the Innovation Authority for a research and development budget support grant for the company's development of cellular therapy for the treatment of ALS amounting to NIS 12.3 million.
- **IsletRx:** On December 19th Kadimastem announced on successful results of its preclinical proof-of-concept (POC) study of IsletRx.

Financially, on March 11, 2020, Kadimastem raised additional capital from its stakeholders in 33.9 Agorot per share, 20% higher than average share price 30 days before closing. Current number of shares is 124.2M; We assume the company will raise capital by the end of the year.

In our view, Kadimastem has the ability to replace the function of damaged cells, such as in the case of ALS. The company offers a cutting edge cell therapy technology, introducing an innovative approach and creating hope where conventional therapy fails. **Should the final results for their phase I/IIa trial also prove positive, this will position Kadimastem as a potential major player in the ALS market. This will also serve as proof of the potential of the company's platform which can be used to treat additional indications in the future.**

Furthermore, the regulatory status of the product and future positive results of negotiations with the FDA will be the next value creating milestone, as Investors are looking for investments at this stage. For example, **On 2019 Bluerock (preclinical stage) was acquired by Bayer in \$600M; Semma Therapeutics (preclinical stage) was acquired by Vertex in \$950M**

Also, the advancement in the Diabetes Cell Therapy program, specifically in the preclinical stage, position Kadimastem as a potential major player in the Diabetes market and are expected to serve as value creating milestones to the company, especially in the view of potential investors and strategic partners.

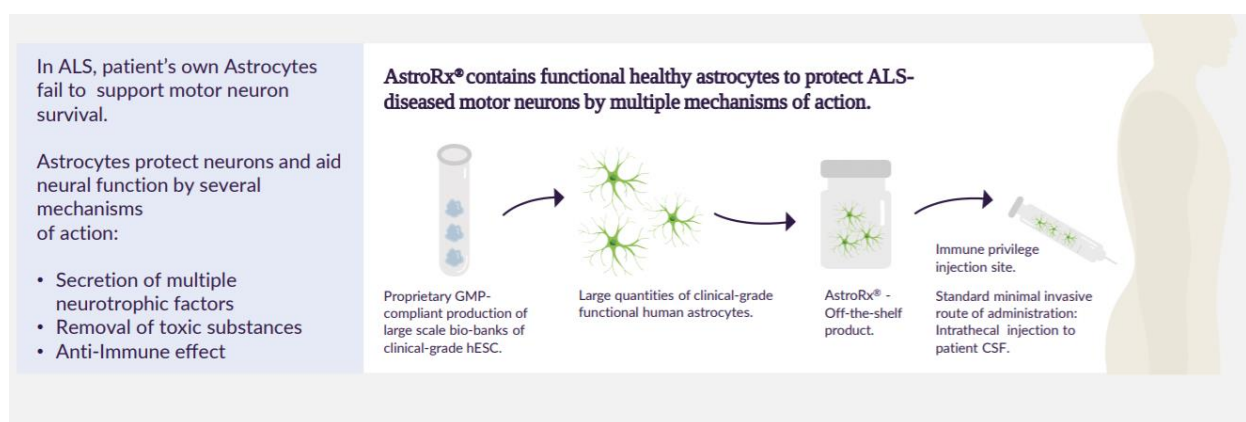
Based on Kadimastem's clinical progress, we maintain the company's value at NIS 119.9M; Target price is updated due to recent capital raising to NIS 0.96.

Executive Summary

Investment Thesis

Kadimastem Ltd. (hereinafter “the Company” and/or “Kadimastem”) is an Israeli publicly-traded specialty biopharmaceutical company focused on the development of stem cell-based therapies.

Indication 1: In March 2018 it began its first clinical trial, a phase I/IIa study using astrocytes, for treating ALS, which is expected to be completed by August 2020. There are just two drugs currently approved by the FDA for treating ALS – Rilutek (riluzole), approved in 1995, which now has several generic alternatives, and Radicava (edaravone), which received FDA approval in May 2017. None of these can reverse or even halt the progression of ALS. While riluzole is a glutamate antagonist that has been shown to extend the life of ALS patients by up to 3 months,¹ Edaravone is a free radical scavenger that delays progression of disability.



Source: Kadimastem

A stem cell-based therapy (consisting of mesenchymal stem cells), Neuronata-R, which is marketed by Corestem and has been approved in South Korea since 2014. Corestem is looking to apply for US approval.

Another stem cell-based therapy (also based on mesenchymal stem cells) is BrainStorm Cell Therapeutics' (BrainStorm) NurOwn, which is currently undergoing a pivotal phase III clinical trial at six U.S sites. If the trial is successful, the company is expected to launch NurOwn by 2020. Both the therapies (Neuronata-R and NurOwn) require isolation of mesenchymal stem cells from a patient and development into the final product. The whole process takes several days (e.g. NurOwn needs about 28 days) and requires a laboratory for isolating and processing of the cells. This provides a huge challenge that AstroRx by Kadimastem doesn't have to face given the fact that it's an off-the-shelf product.

The Global ALS market valuation is expected to surpass \$841.6 million by 2023, with a CAGR of 7.89% over the forecast period (2018-2023)². This growth will be driven by the launch of new pipeline products. Currently, the highest-selling drug in the market is Mitsubishi's Radicava (edaravone)³.

Indication 2: For its diabetes program, the company has also signed a memorandum of understanding with Defymed, a France based manufacturer of medical devices, to jointly develop a device for the treatment of diabetes. The medical device will be targeted at diabetic patients who currently take insulin to manage their blood glucose levels. The global human insulin market was valued at \$42.9 billion in 2017 and is projected to register a CAGR of 8.8% during the period 2018-2023, due to the rising number of diabetic patients, growing geriatric population,

¹ Petrov, D., et al., *ALS Clinical Trials Review: 20 Years of Failure. Are We Any Closer to Registering a New Treatment?* Frontiers in Aging Neuroscience, 2017. 9: p. 68.

² <https://www.marketresearchfuture.com/reports/amyotrophic-lateral-sclerosis-market-5822>

³ <https://www.globenewswire.com/news-release/2019/01/25/1705552/0/en/1-2-Billion-Million-Amyotrophic-Lateral-Sclerosis-Market-2018-Opportunity-Analysis-and-Forecast-to-2027.html>

technological advancements in insulin delivery devices, and increasing population exposure to risk factors leading to diabetes⁴. There are emerging trends in the insulin market that include increased research and development of novel mechanisms and increased academia-industry collaborations for drug development. Additionally, there is an increased demand for automated injection devices like insulin pumps or pens which offer safe and easy drug delivery options⁵. Even though there are many alternatives, the biological activity is the most important. Although the market is highly competitive, we contend that it will gladly adopt companies with innovative mechanisms for addressing diabetic patient needs, to enter and grow.

In recent years there is huge hype in the cell therapy treatment market, big companies are showing interest in these new technologies so the market is constantly growing. The increased prevalence of chronic and genetic diseases has led to the high demand for better medicines and advanced therapeutics. The existing therapies mostly treat the symptoms of the disease. There was an impending need to identify the root causes of diseases and then treat them accordingly. This need was effectively met with the advent of regenerative medicines. Stem cells represent a centrepiece of regenerative medicine and a sub-segment of the cell therapy category. The indefinite self-renewal and differentiation properties present stem cells as frontiers of regenerative medicine, enabling their application in a wide range of disorders. The global stem cell therapy market is fairly concentrated with the presence of big as well small and medium organizations. Increasing funding from the government and other public and private organizations is leading to growing focus on stem cells and driving enormous stem cell research.

In addition, rising awareness and proven effectiveness of stem cell therapy products are the prominent driving factors for the global stem cell therapy market. Hence, with more research and developmental activities, more stem cell therapy products are expected to receive regulatory approval and be launched in the market, bringing about a revolution in the healthcare industry⁶.

⁴ <https://www.psmarketresearch.com/market-analysis/human-insulin-market>

⁵ <https://www.technavio.com/research/insulin-market>

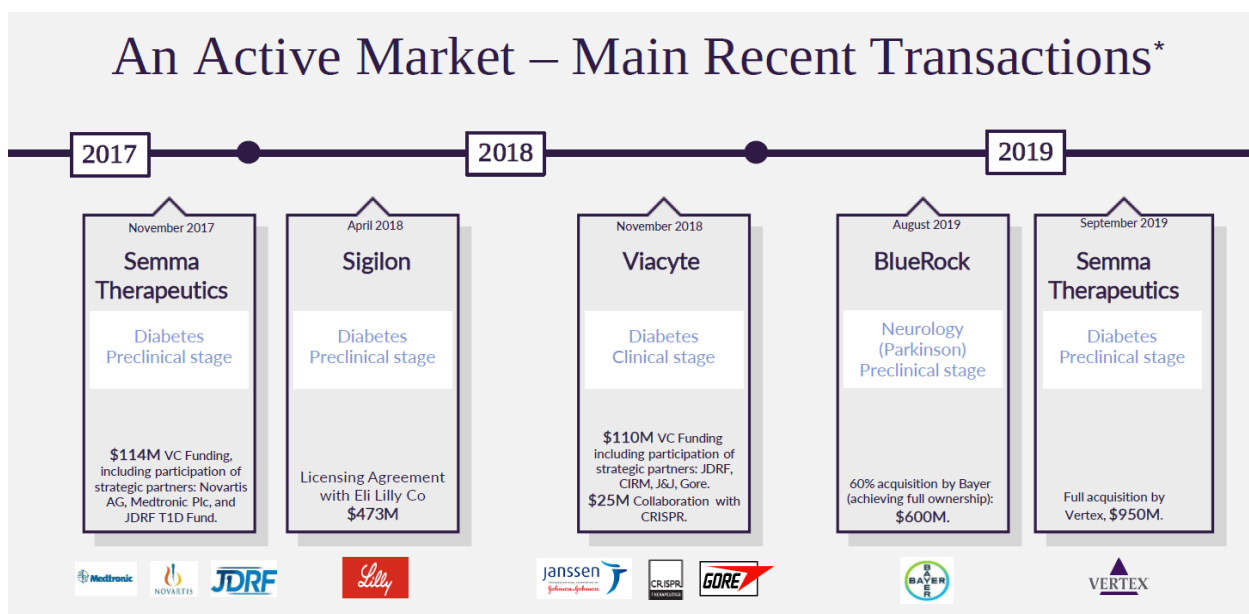
⁶ <https://www.prnewswire.com/news-releases/global-stem-cell-therapy-market-to-reach-11-billion-by-2029-bis-research-300911365.html>

Kadimastem has the ability to replace the functioning of damaged cells, such as in the case of ALS. The company offers a cutting edge technology of cell therapy, introducing an innovative approach and creating hope where conventional therapy fails. The following graphic shows the advantages of Kadimastem's technology which uses off-the-shelf stem cells instead of patient to same patient stem cells.

KADIMASTEM		
	Cells from Bio-Bank to Off-the-shelf Product (Allogeneic)	Cells from patient to same patient (Autologous)
Healthy source of cells	✓	✗ Cells from patient 'Disease in a Dish' technology
Off-the-shelf product	✓	✗ Per patient, "Bedside" tailormade service
Central, robust, repeatable manufacturing	✓	✗ Per patient, Invasive procedure for cell retrieval
Large scale	✓	✗ Per patient, limited scale-up possibility
Cell banks	✓	✗ Per patient, small scale service
Standardized product	✓	✗ Per patient service
Cost effective	✓	✗ Per patient service

Source: Kadimastem

In viewing of recent deals within Kadimastem domain, we see great potential. On 2019 BlueRock (preclinical stage) was acquired by Bayer in \$600M; Semma Therapeutics (preclinical stage) was acquired by Vertex in \$950M. More deals are presented below:



(source: company's investors deck, 2020)

Pipeline Summary

Kadimastem has an ongoing phase I/IIa trial for its lead product, AstroRx (consists of astrocytes which are key cells for adequate brain formation and regulation of cerebral blood flow as well as for the maintenance of neuronal metabolism, neurotransmitter synthesis and exocytosis, and synaptic transmission⁷). It is manufactured from human embryonic stem cells using a proprietary process. The data from the trial will shed light on the safety and efficiency of the treatment.

In ALS disease, the motor neurons are damaged and there is no astrocyte support. AstroRx is expected to provide relief to patients by replacing the patient's malfunctioning astrocytes, which will protect the damaged motor neurons and help in significantly slowing down the progression of the disease.

The company enrolled its first patient on April 26, 2018. Patient recruitment is on-going at the Department of Neurology of the Hadassah Ein-Kerem Medical Center, Israel. The study is expected to be completed by Q3,Q4-2020 (or even earlier), when the company will likely announce details of AstroRx's efficacy and safety demonstrated in the clinical trial.

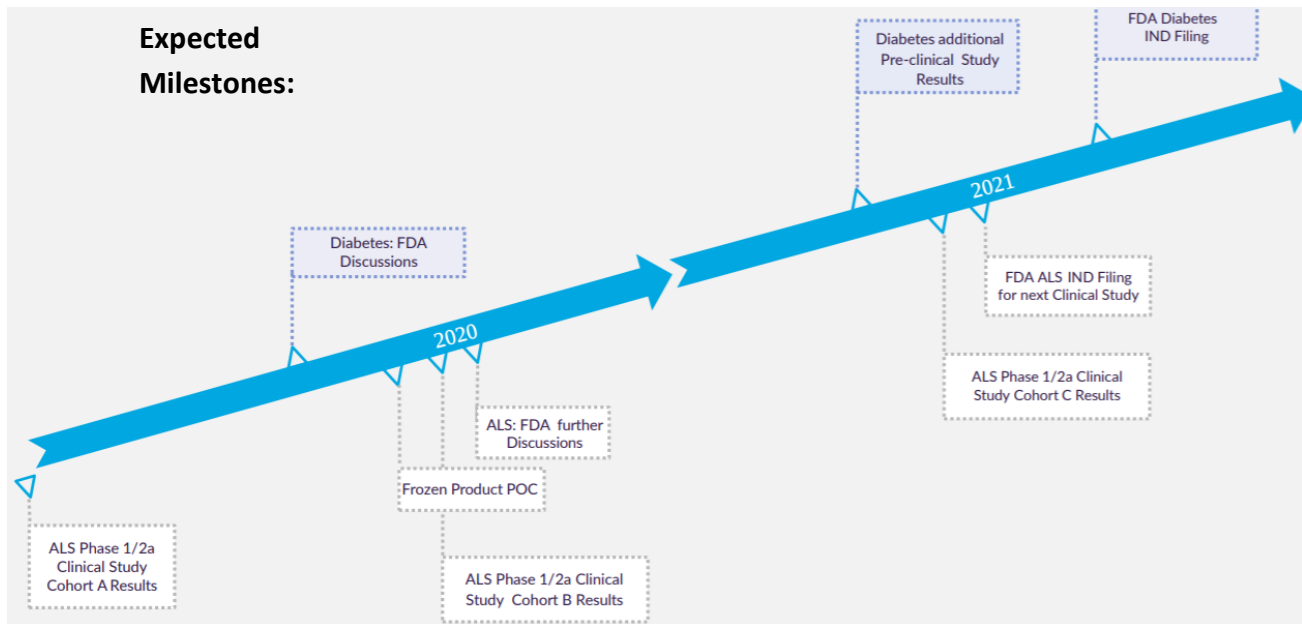
On September 24th Kadimastem announced on positive interim results from its first ALS cohort for AstroRx. As part of an interim analysis initiated by the company with the aim of examining the initial efficiency of AstroRx and conducted after all five patients in the first group completed follow-up visits for a period of 3 months after treatment, a preliminary result of statistical significance was observed indicating a significant slowdown in the rate of deterioration. No serious side effects were reported related to treatment within the experimental setting.

The five patients included in group A received the low dose of AstroRx cells. Initial efficacy was based on the standard (Standard Gold) ALSFRS-R (ALS Revised-Scale Rating Functional) which is the measure of the rate of disease deterioration by monitoring different motor activities of patients over time. On April 18th, 2019 Kadimastem received approval from the Ministry of Health to move to cohort B.

On November 17th the company announced on its intention to submit an amendment of its ongoing Phase 1/2a clinical trial with the purpose of assessing the safety and efficacy of a repeated low dose administration of AstroRx® in cohort C in 2 consecutive injections separated by an interval of 2-3 months, rather than the repeated administration of the medium dose as originally planned.

On November 19th the company also announced on successful results from its preclinical proof-of-concept study of IsletRx (an "off-the-shelf" cell product for the treatment of Insulin Dependent Diabetes), incorporating a microencapsulation solution developed by the company. IsletRx is comprised of highly purified functional human pancreatic islet cells integrated with a microencapsulation technology developed by the company. The results indicate on the Safety & Efficacy of IsletRx for the treatment of Insulin Dependent Diabetes. IsletRx balances and maintains normal blood glucose levels in immunocompetent diabetic animal model, achieving prolonged therapeutic effect while not activating host immune system response. Based on these results, Kadimastem continues to advance its IsletRx development program towards the clinical stage. The Company plans to engage in discussions with the U.S. Food and Drug Administration (FDA) during H1 2020.

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/31470787>



Source:Kadimastem

Currently there is no cure for ALS despite numerous clinical trials; current therapies are palliative and only extend survival a few months. Stem cell therapy is considered an attractive approach for ALS that addresses the complex disease pathogenesis through multiple potential mechanisms. The premise of stem cell therapy for ALS is based on improving the diseased microenvironment. While stem cells are unable to directly replace diseased motor neurons, transplanted stem cells secrete neurotrophic factors and differentiate into supportive cells, such as astrocytes and microglia, generating a neuroprotective milieu that can slow degeneration of motor neurons⁸.

⁸ <https://www.tandfonline.com/doi/abs/10.1080/13543784.2019.1627324?journalCode=ieid20>

Recent Updates

AstroRx®: The first of 3 cohorts participating in the Phase 1/2a Kadimastem clinical trial for the treatment of ALS showed promising results 6 months after treatment using the gold standard ALSFRS function test.

The spread of the corona virus affects the conduct of clinical trials in Israel and around the world. This is especially true for ALS patients who's lung function is at risk. Kadimastem has completed the treatment and monitoring of the first cohort (A) as well as the treatment of the second cohort (B). In accordance with the regulations put in place by the clinical trial safety committee and the local ministry of health, it has been decided that cohort B will continue to be monitored for safety purposes and to collect trial results. Cohort C that has not yet begun the trial will be postponed until safety can be assured as this trial requires patients to undergo procedures in a hospital environment.

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Upcoming Potential Catalysts

Program	Event	Significance	Timeline
AstroRx trial with ID NCT03482050: A Phase I/IIa, Open-Label, Dose-escalating Clinical Study to Evaluate the Safety, Tolerability and Therapeutic Effects of Transplantation of Astrocytes Derived From Human Embryonic Stem Cells (hESC), in Patients With Amyotrophic Lateral Sclerosis (ALS)	Results on drug safety and efficacy will be declared. Information on measurable parameters such as improvement in muscle strength and quality of life due to the use of AstroRx will be reported.	High	2021
IND filing for ALS		High	H2-2021
IsletRX additional preclinical safety and efficacy proof	With Kadimastem internal microencapsulation solution With IsletRx	Achieved	Mid 2020
IND filing for Diabetes		High	H2-2021

Appendices

Appendix A - Financial Reports

Balance Sheet (NIS 000s)

As at:	12/31/2019	12/31/2018
Cash And Cash Equivalents	46	11,108
Net Receivables	1,534	1,274
Total Current Assets	1,580	12,382
Property, Plant and Equipment	1,619	1,427
Restricted Cash	506	556
Total Assets	7,289	14,616
Liabilities to suppliers and service providers	6,703	4,674
Accounts Payable	2,620	2,024
Advanced Deposit	467	587
Total Current Liabilities	16,647	7,285
Total Non-Current Liabilities	2,668	593
Total Liabilities	19,315	7,878
Shareholder's Equity	(12,026)	6,738
Total, Liabilities + Equity	7,289	14,616

Statement of P/L (NIS 000s) for the period of 12 months ending on:

<i>Six-Months Ending</i>	<u>12/31/2017</u>	<u>12/31/2018</u>	<u>12/31/2019</u>
Total Revenue	684	0	0
Cost of Revenue	48	0	0
Gross Loss (Profit)	636	0	0
Research & Development Expenses	14,870	16,654	17,822
Selling, General & Administrative Expenses	6,603	6,962	6,883
Operating Loss	20,837	23,616	24,705
Net Financial Expenses	766	403	567
Earnings Before Taxes	(21,603)	(24,019)	(25,272)
Income Tax	175	51	186
Net Loss	21,428	23,968	25,086

Credit to Expert: Dr. Hadar Cohen-Halevi, Chen Yakar

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