

H1-2018 Update

27 September, 2018



Kadimastem has raised NIS 15M which will fund clinical and pre-clinical development for cellular therapy; target price unchanged.

Primary Exchange: TASE

Ticker: TLV:KDST

Sector: Healthcare

Industry: Pharmaceuticals

Data as at 27 September, 2018

(Source: TASE)

Closing price: NIS 0.71

Market cap: NIS 43.6M

of shares: 61.6M

Stock performance (12 mos.): -54%

Daily-trading-vol. (12 mos.): NIS 280k

Stock target price: NIS 0.85

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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 phase – 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

Kadimastem announced a significant event on September 6, 2018:

NIS 15M in capital raised to see the company through till mid-2019

- The Company raised NIS 15M, by private placement from a number of investors, including the controlling shareholders of the Company, Prof. M Revel and Mr. J Rogery. The company continues to advance negotiations with other investors and estimates that it will raise the NIS 5M needed to complete the financing round shortly.
- Funds raised from the controlling shareholders at NIS 0.65 per share, a very slight discount compared to the trading price of the company's shares at the time; NIS 0.68. This affirms investor confidence from those most well acquainted with its activity.
- In conjunction with the company's existing cash balance and capital resources, we expect these funds to finance the company's operations until mid-2019.

Kadimastem published its H1-2018 Report on 30 August, detailing the following:

The company had no revenue in H1-2018. Net loss for the period amounted to NIS 11M compared to NIS 11.9 million for H1-2017.

- The Company has a capital deficiency of NIS 2.7 million as of June 30, 2018, compared to NIS 4.3 million as of December 31, 2017. The main change is due to the expenses incurred by the company during this period for clinical development
- The Company's auditors gave it a "live business" comment.

On the clinical side, the company has won several awards and its researches have been published in leading journals attesting to the scientific basis of the company's technology.

- Recall that the Company is expected to complete Phase I / IIa clinical trials that examine the safety and efficacy of the AstroRx by 2020; Results of the first group of clinical trials are expected to be published by mid-2019.
- The company received a bilateral grant from Australian and Israeli government entities. The joint research grant is part of a bi-national program to examine and develop the integration of the company's technology for the treatment of diabetes.
- In the field of diabetes, the company is in pre-clinical stages of developing the product Encapsulin. As part of the development, the company is collaborating with the French medical device company Defymed to examine encapsulation technologies (cell wrapping in membranes that are isolated from the patient's immune system). A joint clinical trial will begin in 2019.

We maintain our estimation for the company's equity value at NIS 52.1M (\$14.6M) corresponding to a target price ranging between NIS 0.77 and NIS 0.93; a mean of NIS 0.85.

- See below for details on our valuation update, and in our [Initiation of Coverage report dated June 12, 2018](#) for details on our valuation methodology.

Updates for H1-2018

Clinical Development

Approval for a research grant from the Australian Government and the Innovation Authority to Examine an Integrated Diabetes Solution

The company received approval from the Australian Government and the Innovation Authority of the Israeli Ministry of Economy to receive a joint research grant as part of a bi-national program to examine and develop the company's technology for the treatment of diabetes, together with dedicated medical equipment developed by the Australian Foundation for Diabetes Research. The project budget requested by the Company from the Innovation Authority, which will be spread over a period of three years (the length of the duration of the plan), and will amount to NIS 3 million, of which the Innovation Authority (which will participate in half of it) approved NIS 1 million for the first year.

Awarded honors in presentation of the company's technology at the prestigious European ALS Conference at Oxford University

During a prestigious European ALS conference held at Oxford University in England, the company presented its scientific work on cellular therapy. The work was awarded with honors from a pool of hundreds of research papers presented at the conference.

Published a scientific article about the company's cellular treatment of ALS in a prestigious scientific journal in the field of cellular therapy

On June 6, 2018 the company published a scientific article in the prestigious medical journal article discussing the flagship product of the company, AstroRx. The results describe the efficacy and safety results of the product in the model on animals and the various mechanisms that prevent the death of motor neuron cells affected by ALS. The results described in this article form the basis of the clinical trial currently being conducted by ALS patients using AstroRx at Hadassah Ein Kerem Hospital.

Agreement signed to examine the feasibility of a combined solution for the treatment of diabetic patients with Defymed.

On April 20, 2018, the company signed a memorandum of understanding with the medical device company SAS Defymed, to examine the integration of the technologies of both companies for the treatment of diabetes. On June 14, 2018, the Company signed an agreement to examine the feasibility of a combined solution for the treatment of diabetic patients with Defymed.

Capital Raising

Completion of NIS 15 million in capital raising at a price of NIS 0.65 per share

The company raised private placements from several investors, including the controlling shareholders of the company, Professor Michel Revel and Mr. Julian Rogery. The company announced that it is continuing to advance negotiations with other investors regarding the completion of another round of financing, and believes that it will complete the round of financing in the near future. The current funding round is for total consideration of NIS 20M, meaning NIS 5M remains outstanding. These funds will be sufficient for the company to realize its strategic goals set up until mid-2019. The initial NIS 15M was raised at a relatively low discount on the market price in the month before the issue (about 70 Agorot per share).

In addition, the cash balance as of June 30, 2018 is approximately NIS 2.4 million, while the cash used in its current operations is approximately NIS 9.3 million for H1-2018. In other words, the company burns approx. NIS 4.7 million per quarter.

Financial Results

Revenues, none were recorded in H1-2018. Revenues for H1- 2017 were due to the linear recognition of revenues from the Merck Serono agreement, which was spread over the three-year agreement period. The agreement with Mark Serono ended in July 2017.

Research and Development expenses totaled NIS 7.3M in H1-2018 a significant decrease compared to these expenses in H1-2017, mainly due to the addition of expenses in respect of options and payments in 2017. Excluding these expenses, total expenses in H1-2018 were NIS 7 million, compared to NIS 9.9 million in H1-2017; this was mainly due to a decrease in the cost of subcontractors, which occurred during the parallel period due to preparations for the clinical trial, compared to H1-2018, which was only partially affected by the clinical trial.

General and administrative expenses remained relatively constant compared to the corresponding period and amounted to NIS 3.4 million.

Total loss for the first half of 2018 amounted to NIS 11 million compared to the corresponding period in 2017, in which the loss amounted to NIS 11.9 million

Capital deficiency of the company amounted to NIS 2.7 million at June 30, 2018, compared to NIS 4.3 million at December 31, 2017. The change was due to clinical development expenditure during the period.

Net loss to the Company of NIS 11 million and a negative cash flow from operating activities of NIS 9.4 million for the six-month period ended June 30, 2018.

The Company's auditors gave it an on going concern comment.

Analysis

Kadimastem is a public Israeli company specializing in regenerative medicine. In March 2018, the company began its first clinical trial, stage I/IIa, with human astrocytes (AstroRx®) to replace the defective astrocytes in ALS patients. The unique characteristics of AstroRx® are expected to significantly slow the progression of the disease, as the company has demonstrated in its preclinical trials. The Phase I/IIa clinical trial is expected to be completed by mid-2020.

Only two drugs have so far been approved by the FDA to treat ALS, and none of the drugs can reverse the disease. In the stem cell field, there is one treatment (based on mesenchymal stem cells) marketed by Corestem and approved in South Korea since 2014. Corestem may apply for approval in the US towards the end of 2018 or the beginning of 2019.

Another treatment based on stem cells (also based on mesenchymal stem cells) is BrainStorm Cell Therapeutics, a public Israeli company, with its lead asset currently undergoing Phase III clinical trials. If the trial succeeds, the company is expected to launch its leading product by 2020.

In the above two treatments, it is necessary to isolate the mesenchymal stem cells from the ALS patient and develop them into the final product. The process takes a few weeks (for example, the Brainstorm product requires about 28 days) and a laboratory for cell isolation and processing is required. This limits the ability of Corestem and Brainstorm to provide treatment for ALS patients, which are spread over different regions. Kadimastem's AstroRx®, as a shelf product, does not have these limitations.

In the area of diabetes, the company's treatment, Encapsulin, is designed for diabetics who are currently taking insulin to manage their blood glucose levels. The company is in the preclinical stage. The product is made up of insulin-producing and glucagon-producing products in response to external glucose levels. The company is examining and promoting cooperation in the field of encapsulation in order to select a partner with technological capabilities suitable for implementation of the company's cellular product for the

treatment of diabetes. As part of this strategy, the company recently signed a memorandum of understanding with Defymed, a French medical device company, to conduct a feasibility study in the framework of preclinical trials deploying Kadimastem's cells with Defymed's device to assess the effectiveness of the combination.

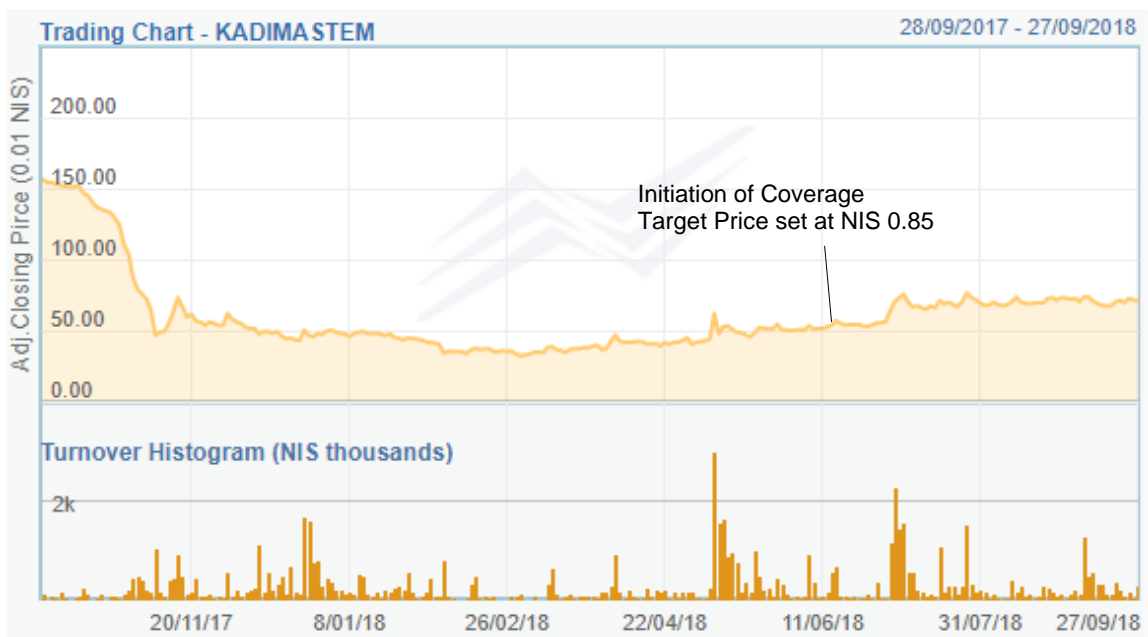
2019 will be a crucial year for Kadimastem with the forecasted release of early-stage clinical trial results for its ALS treatment and a POC trial for its diabetes treatment. Both have the potential to impact the company's strategic position within the stem cells domain.

In view of the above, we maintain our estimation for the company's equity value at NIS 52.11M (\$14.64M) corresponding to a target price ranging between NIS 0.77 and NIS 0.93; a mean of NIS 0.85.

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	Mid-2019
AstroRx pivotal clinical trial	Commencement of a pivotal clinical trial.	High	2020
Encapsulin	Proof of concept pre-clinical test using Defymed's MailPan device and Kadimastem's islet-of-Langerhans-like cell clusters to evaluate the efficacy of the combination in treating diabetes.	High	Mid-2019

12-month stock movement



Appendix – Financial Statements

Balance Sheet (NIS 000s)		
As at:	12/31/2017	6/30/2018
Cash And Cash Equivalents	9,549	2,372
Net Receivables	911	983
Total Current Assets	10,460	3,355
Property, Plant and Equipment	1,068	1,265
Restricted Cash	604	600
Total Assets	12,132	5,220
Liabilities to suppliers and service providers	4,917	4,497
Accounts Payable	1,650	1,503
Advanced Deposit	0	662
Short Term Credit, and others	772	773
Total Current Liabilities	7,339	7,435
Total Non-Current Liabilities	513	513
Total Liabilities	7,852	7,948
Shareholder's Equity	4,280	(2,728)
Total, Liabilities + Equity	12,132	5,220

Statement of P/L (NIS 000s)			
<i>Six-Months Ending</i>	<u>30/06/2017</u>	<u>31/12/2017</u>	<u>6/30/2018</u>
Total Revenue	(589)	(95)	0
Cost of Revenue	41	7	0
Gross Loss (Profit)	548	(548)	0
Research & Development Expenses	8,895	5,975	7,323
Selling, General & Administrative Expenses	3,151	3,352	3,401
Operating Loss	11,598	9,239	10,724
Net Financial Expenses	347	419	284
Earnings Before Taxes	11,945	9,658	11,008
Income Tax	(62)	(113)	(51)
Net Loss	11,883	9,771	10,957

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