



KADIMASTEM

Cells to cure diseases

November 2019
(TASE: KDST)

Disclaimer

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In this presentation, in slides 7, 8, 14, 20 & 23 the company included projections, estimates and assessments, as are known to the Company at the time of preparation of this presentation, referring to the Company and including, inter alia, forward-looking information as defined in the Securities Law, 5728 – 1968, based on subjective estimates on the part of the Company in respect of its development potential and based on initial information and documents the Company received from professional entities relevant to the Company’s development plans.

Forward-looking information is uncertain and mostly is not under the Company’s control and the realization or non-realization of forward-looking information will be affected, among other things, by the risk factors characterizing the Company’s activity, as well as developments in the general environment and external factors affecting the Company’s activity. The Company’s results and achievements in the future may differ materially from those presented in this presentation and the Company makes no undertaking to update or revise such projections or estimates and does not undertake to update this presentation.

This presentation does not constitute a proposal to purchase the Company’s securities or an invitation to receive such offers. Investment in securities in general and in the Company in particular bears risks. One should take into account that past performance does not necessarily indicate performance in the future.



KADIMASTEM

Cells to cure diseases

A clinical stage cell therapy company applying a unique
TECHNOLOGY PLATFORM for the development and production of
OFF-THE-SHELF cell treatments for multiple diseases.

November 2019
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Turning science into blockbuster therapy



Prof. Michel Revel
Founder & Chief Scientist

Prof. Emeritus of molecular genetics.
The Weizmann Institute of Science.

A world leading expert in cell therapy and regenerative medicine

Bringing over 40 years of successful experience in development and global commercialization of advanced biotechnology products.

Israel prize laureate for the development of the REBIF[®], a Multiple Sclerosis blockbuster drug, sold worldwide by Merck at \$1.7B annually (2016*).



We are leading the path to a paradigm shift, from conventional drugs to regenerative medicine, replacing cells damaged by disease with new healthy functional cells. This regenerative cell therapy promises to bring treatment and cure to millions of patients worldwide.

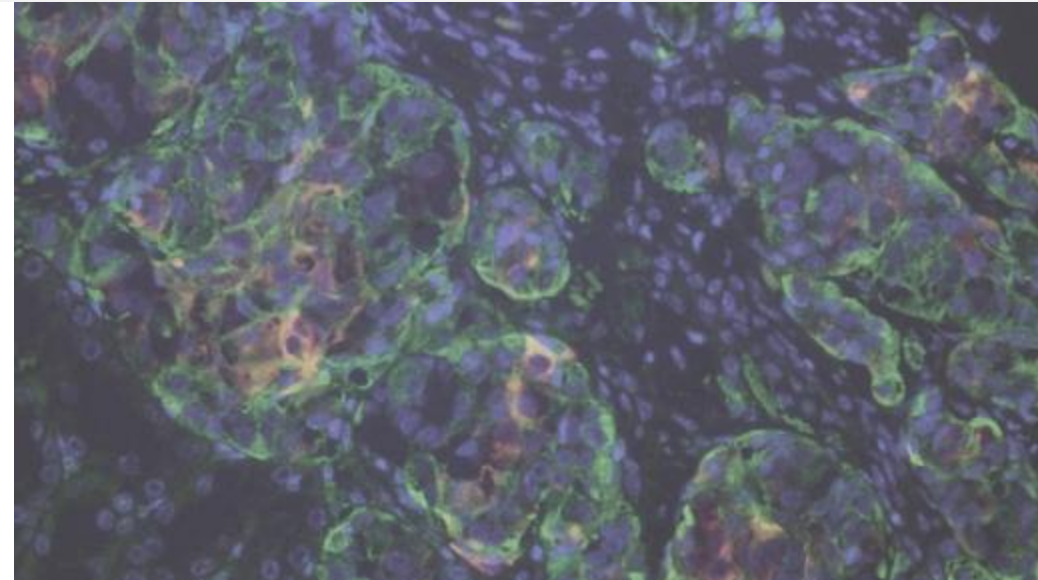


Replacing malfunctioning cells with healthy functional cells to treat complex and rare diseases

Why Cell Therapy?

Unlike conventional drugs, cells are a dynamic bio-product:

- ✓ Replacing malfunctioning cells.
- ✓ Restoring functionality.
- ✓ Releasing beneficial agents.
- ✓ Responding to metabolic processes.





Company Overview

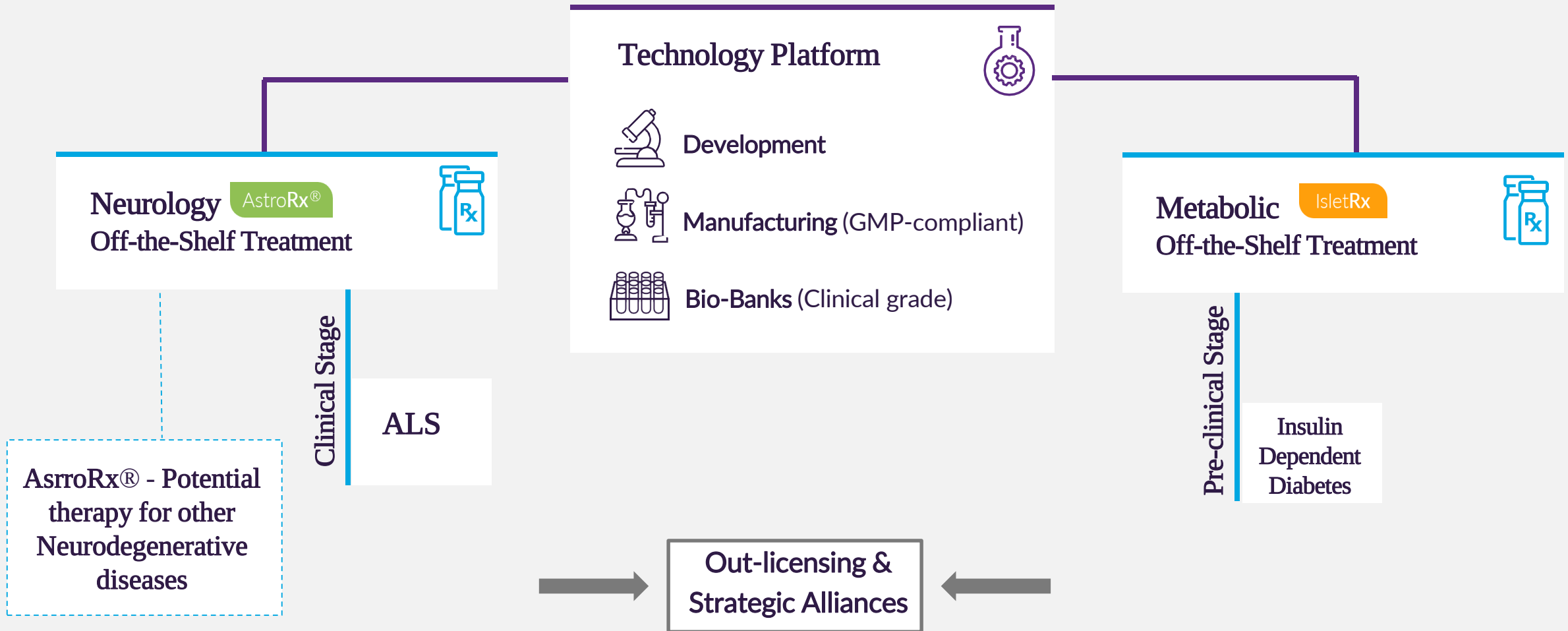
- **Lead Clinical Program:** **AstroRx®**
 - **First company** treating ALS patients with human astrocyte cells (AstroRx®).
 - Sep. 2019: Showing favorable safety & efficacy interim results in cohort A of Phase 1/2a clinical trial. **Statistically significant delay in disease progression was demonstrated (p=0.0023).**
 - AstroRx® for ALS treatment granted FDA Orphan Drug Designation in 2018.
 - AstroRx® - potential therapy for other neurodegenerative diseases.
- **Lead Pre-clinical Program:** **IsletRx**
 - Providing insulin and glucagon secreting cells to cure Diabetes.
 - Nov. 2019: Pre-clinical results demonstrate IsletRx safety & efficacy.
- **Technology Platform:**
 - **Development** - Process development, based on proprietary technology, producing a wide range of cells.
 - **Manufacturing** - Commercial scale bioproduction, GMP-compliant, Clinical grade.
 - **Cell Bio-Banks** - human Pluripotent Stem Cells (hPSC), differentiated cells, and committed cells.
- **Exclusive license, Know-how & Strong IP** (4 extensive patent families).
- **Employees:** 41 (11 PhDs)
- **Total Financing to date** (since Company incorporation, 2009): \$50M
 - Equity: \$38M
 - Grants: \$12M



Horizon 2020
European Union funding
for Research & Innovation

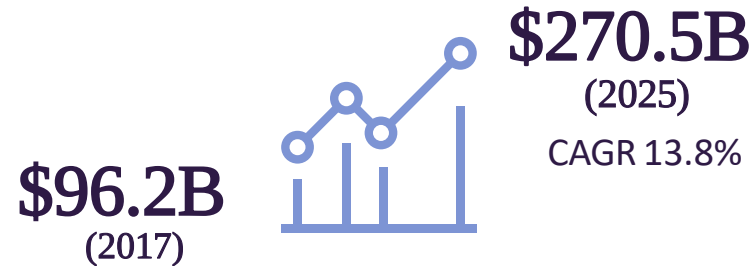


Company Snapshot



The Market Opportunity

The Global Stem Cell Market



Transparency Market Research, September 2017*

Potential Market Drivers



Reimbursement

Insurers implementing new mechanisms supporting the introduction of cell therapy.



Regulatory

Regulatory authorities implementing new policies enabling expedited review potentially leading to accelerated and conditional approval of cell therapy.



Technology

Early players with technological advantages will lead the market with superior treatment options for new indications.



R&D Partnerships

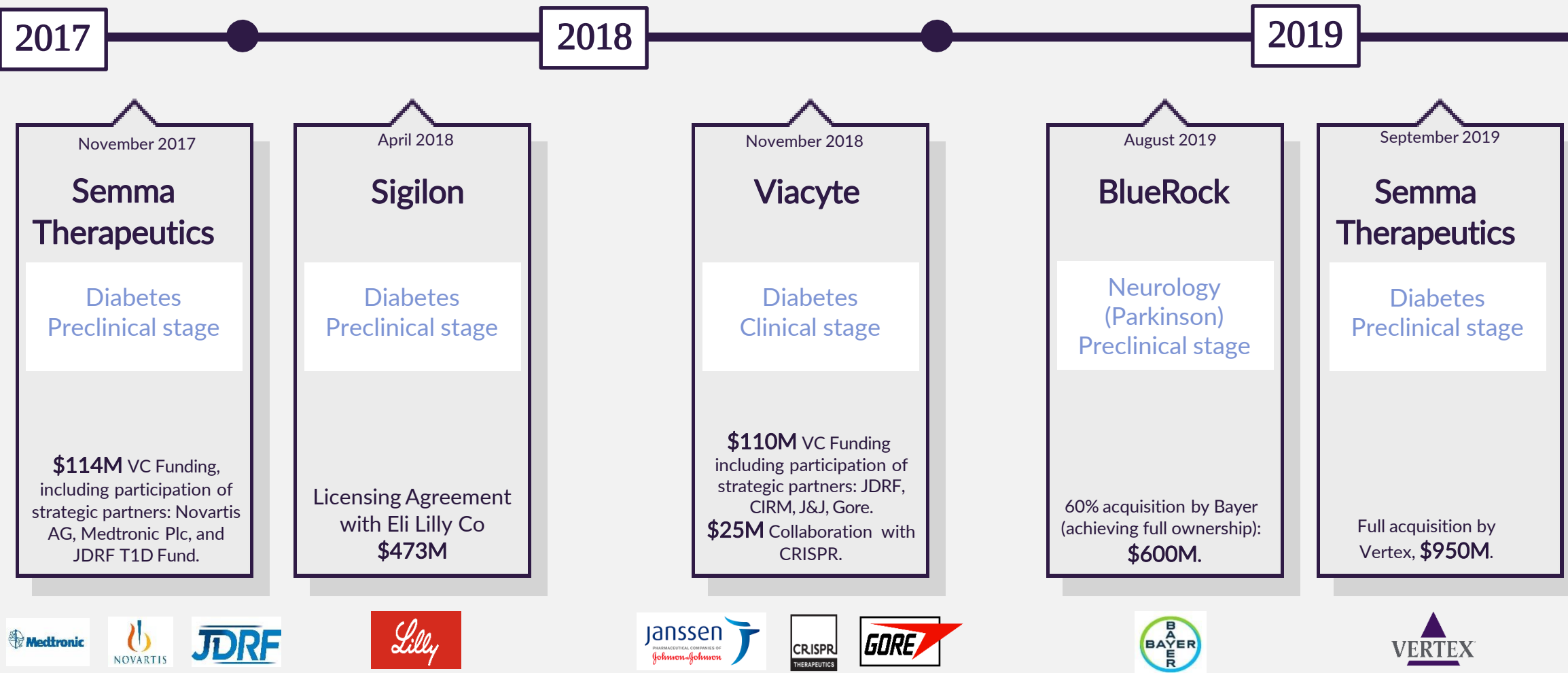
Big Bio-Pharma gaining competitive edge and overcoming lack of internal pipeline via collaborations and M&As with small to mid-cell therapy segment players.



Investments & Financial

Rising awareness to the therapeutic potency of cell treatment attracts funds for research and industry from public, government, and private organizations.

An Active Market – Main Recent Transactions*



To the best of Company's knowledge, base on the following:

- <http://www.semma-tx.com/media1/vertex-to-acquire-semma-therapeutics-with-a-goal-of-developing-curative-cell-based-treatments-for-type-1-diabetes>
- <https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html>
- <https://media.bayer.com/baynews/baynews.nsf/id/Bayer-acquires-BlueRock-Therapeutics-to-build-leading-position-in-cell-therapy>

Our Technology Platform



Development expertise, GMP-compliant Bioproduction,
and Bio-Banking of a wide range of clinical-grade cells



Our Technology Platform

Proprietary expansion and differentiation protocols of cells intended for treatment of multiple diseases

Exclusive license for
Starting Material.



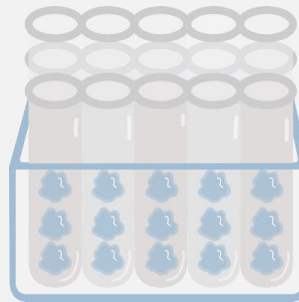
Clinical-grade Embryonic
Stem Cell line

Pluripotent Stem Cell
Expansion



Large scale

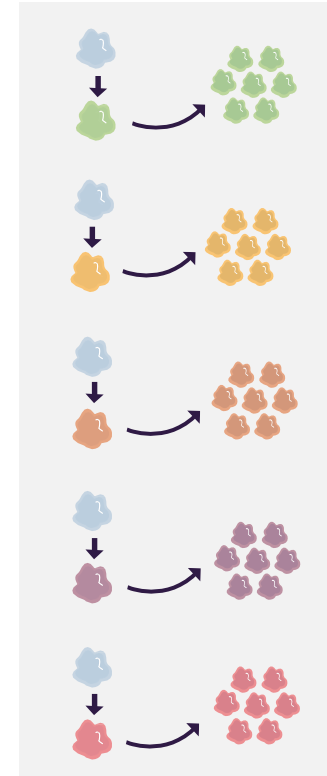
Bio-Banking



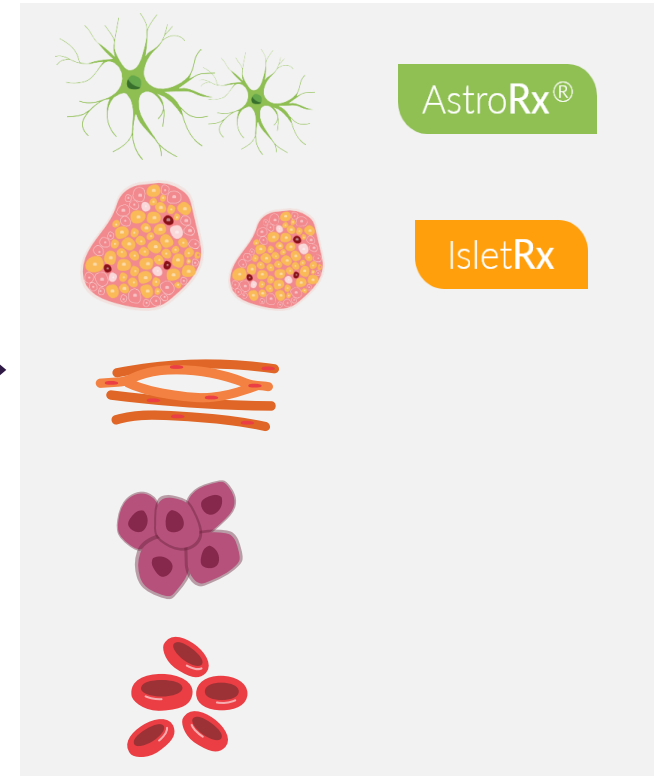
Unlimited # of Pluripotent
Stem Cell Bio-banks

Expansion and differentiation protocols

Large number of well
characterized
progenitor cell lines.



Potential wide range
of cells treating a wide
range of diseases.



Mature Functional
Cells - High potency,
purity and specificity.

AstroRx®

IsletRx



Our Technology Platform - Advantages

KADIMASTEM			
Allogeneic Therapy Cells from Bio-Bank to Off-the-shelf Product		Autologous Therapy Cells from patient to same patient	
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 service
Cell bio-banks	✓	✗	Per patient service
Standardized product	✓	✗	Varies from patient to patient
Cost effective	✓	✗	Per patient service

Neurology Indications



Proprietary off-the-shelf cell product: AstroRx®

Cells: Astrocytes

Lead Clinical Program: ALS

AstroRx® - Potential therapy for other Neurodegenerative diseases

ALS – The hope for a cure



Amyotrophic Lateral Sclerosis (ALS) is a rapidly progressive neurological disease, causing dysfunction in the motor nerves that control muscle movement.

ALS leads to muscle weakness, a loss of motor function, paralysis, breathing problems, and eventually death.

3 FDA approved drugs: Rilutek, Tiglutik, Radicava, extend life expectancy by 3-5 months.



Rare disorder affecting approximately 30,000 people in the US.*



\$6B

estimated annual ALS healthcare costs in US.



450,000

Estimated patients worldwide.*

Currently

NO CURE
for ALS

2-5

years average life expectancy

\$200,000

estimated annual medical expense per patient in US.**

ALS Annual Drug Sales***

2027: **\$1.2B**



2017: **\$187M**

*<https://www.als.net/news/als-therapy-development-institute-and-anida-pharma-partner-to-investigate-potential-treatments-for-als>

**<http://alsfoundation.org/learn/facts.htm>

***<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>



Our Solution

AstroRx[®] for ALS Treatment

First-in-human treatment with astrocyte cells (clinical trial)

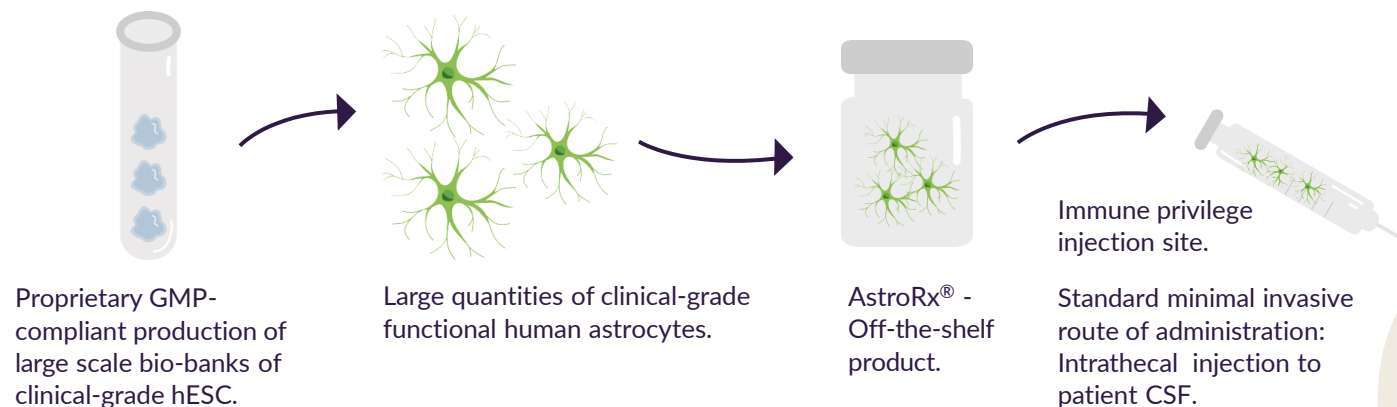
Granted FDA Orphan Drug designation in 2018

In ALS, patient's own Astrocytes fail to support motor neuron survival.

Astrocytes protect neurons and aid neural function by several mechanisms of action:

- Secretion of multiple neurotrophic factors
- Removal of toxic substances
- Anti-Immune effect

AstroRx[®] contains functional healthy astrocytes to protect ALS-diseased motor neurons by multiple mechanisms of action.

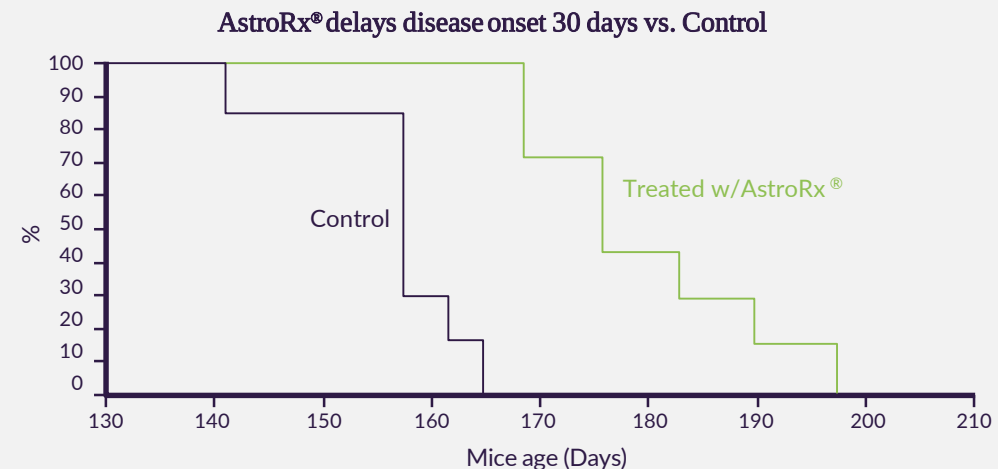
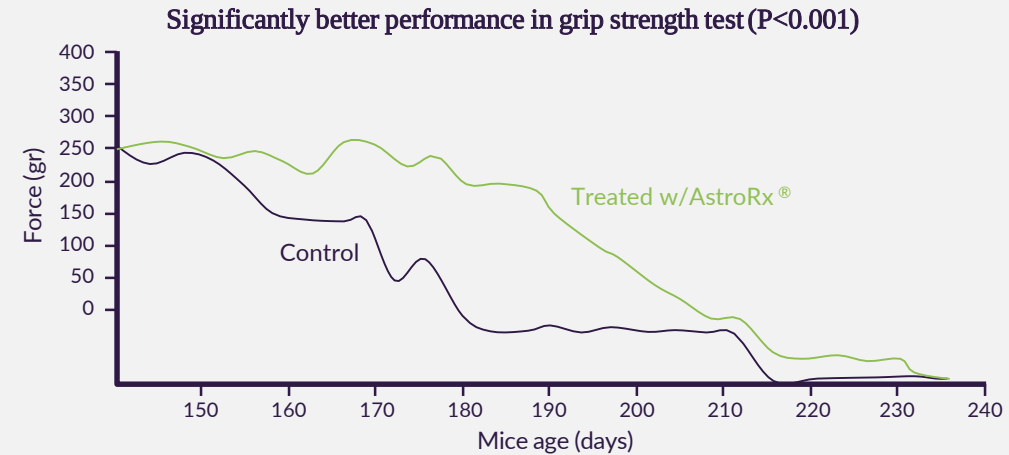




AstroRx[®] – Pre-clinical Safety & Efficacy

Results of animal studies demonstrated the safety and efficacy of AstroRx[®] treatment for ALS:

- Animal model: transgenic hsOD1 mice and rats - the gold-standard for ALS disease.
- Compared to the control group, the AstroRx[®] treatment group showed:
 - ✓ Significantly delayed disease onset.
 - ✓ Significant improvement in motor (muscle) function.
 - ✓ Improved survival rate and life expectancy.
 - ✓ AstroRx[®] injection into the spinal fluid (CSF) enables the dispersion of cells throughout the spinal cord and brain.
 - ✓ Treatment group did not exhibit any adverse clinical signs that could be treatment related.



AstroRx[®] First-in-Human Clinical Trial

Interim Results of Cohort A of Phase 1/2a Clinical Study in ALS Patients

Demonstrating Safety & Preliminary Efficacy



Study Design:

- 21 ALS patients (4 treatment cohorts).
- Cell transplantation (AstroRx[®]) using a standard medical procedure under local anesthesia.
- 3 cohorts of escalating dose & 1 cohort of repeated treatment.
- Study Site: Hadassah Ein Kerem Hospital, Jerusalem.
- ClinicalTrials.gov Identifier: NCT03482050

Study Status:

- ✓ All 5 patients of cohort A were treated with 100×10^6 AstroRx[®]
- ✓ All completed at least 3 months of the follow-up period.
- ✓ Cell injection for cohort B initiated (treatment with 250×10^6 AstroRx[®]).

AstroRx[®] First-in-Human Clinical Trial

Interim Results of Cohort A of Phase 1/2a Clinical Study in ALS Patients

Demonstrating Safety & Preliminary Efficacy



✓ Demonstrating Safety

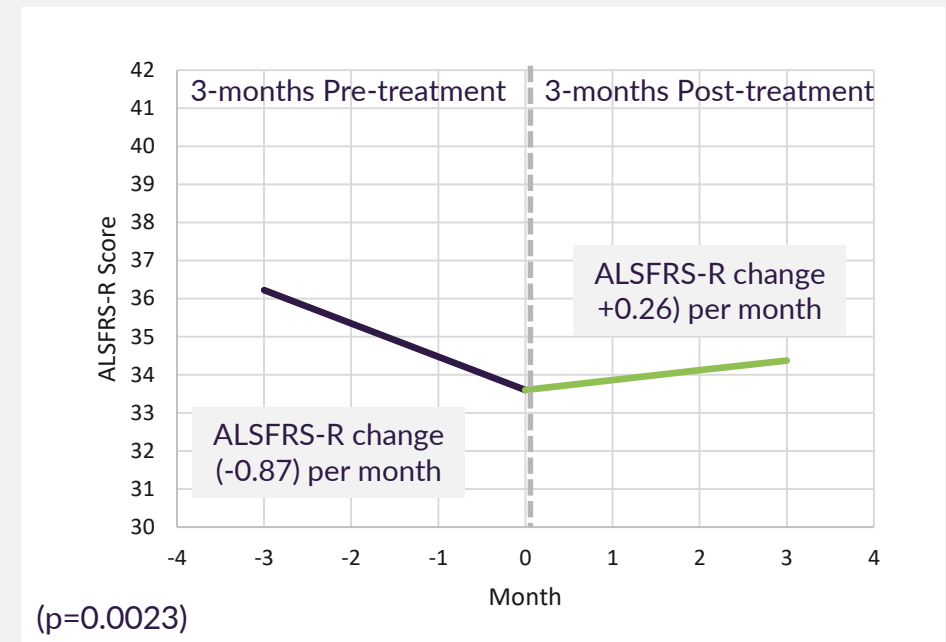
No treatment-related serious adverse events nor dose-limiting toxicities were reported.

✓ Demonstrating Preliminary Efficacy

Disease progression was reduced in the first 3 months post-treatment period compared to the 3 months pre-treatment period, demonstrating **statistically significant decline** in disease progression ($p=0.0023$).

During the 3 months pre-treatment period, the ALSFRS-R decreased at a rate of (-0.87) per month. This rate of decrease is similar to that reported in the scientific literature. The ALSFRS-R change in the 3 months post-treatment was $(+0.26)$ per month (MMRM analysis).

Demonstrating Statistically Significant Decline in Disease Progression (ALSFRS-R* Slopes)



Preliminary efficacy assessment was based on ALS Functional Rating Scale-Revised (ALSFRS-R), the gold standard criteria to assess ALS progression by monitoring patient muscle functions over time.

Metabolic Indications



Proprietary off-the-shelf cell product: **IsletRx**

Cells: Pancreatic Islets

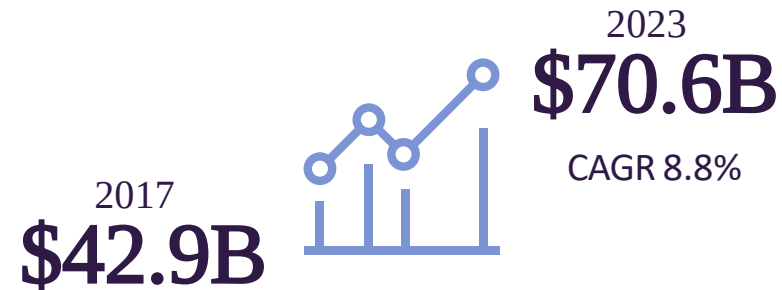
Lead Pre-Clinical Program: Diabetes

Replacing malfunctioning Insulin & Glucagon secreting cells to cure Diabetes.

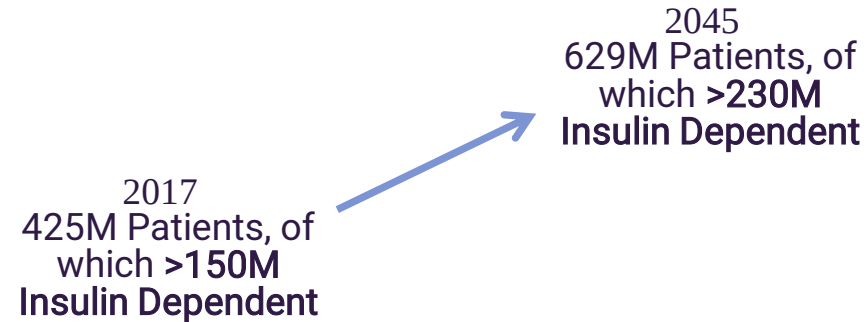
Insulin Dependent Diabetes - An Unmet Need



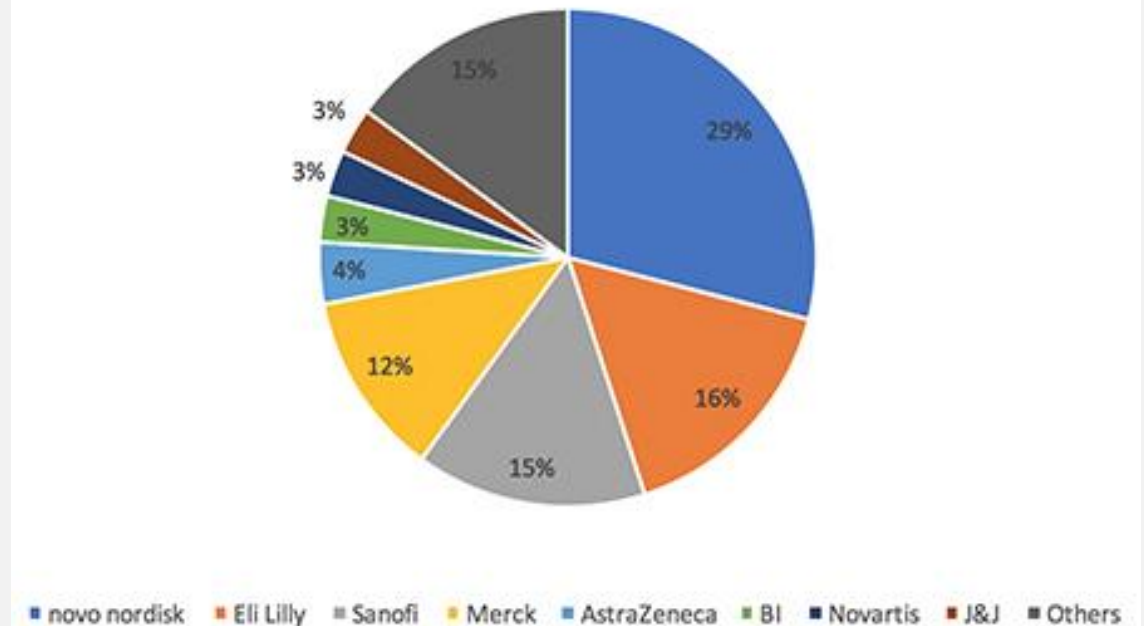
The Global Human Insulin Market**



Diabetes World Prevalence***



The Global Diabetes Market Share (2017)*



*<http://www.pharmexec.com/diabetes-market-china>

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

***Type1 15%: [https://www.medicinejournal.co.uk/article/S1357-3039\(18\)30264-0/fulltext](https://www.medicinejournal.co.uk/article/S1357-3039(18)30264-0/fulltext)

Our Solution

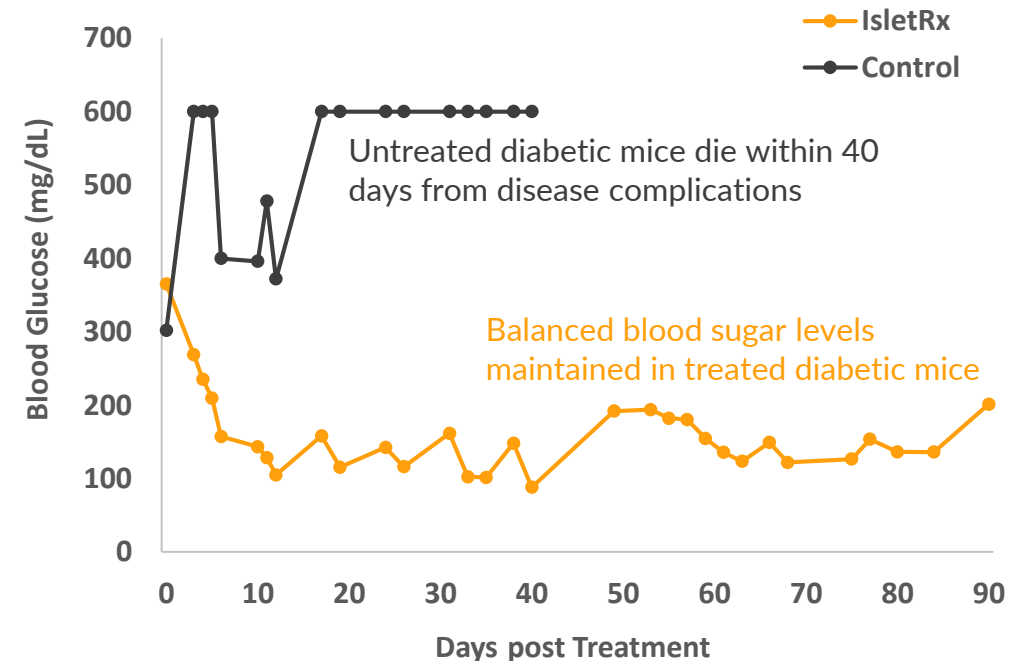
IsletRx to Cure Diabetes



- IsletRx contains functional pancreatic islet cells, secreting Insulin and Glucagon.
- Unique microencapsulation technology protects IsletRx cells from host immune system response, overcoming a major challenge faced by the Cell Therapy industry.
- Proprietary know-how (IP) enables islet cells enrichment & purification.

Pre-clinical results demonstrate:

- ✓ 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.
- ✓ IsletRx does not activate host immune system response.

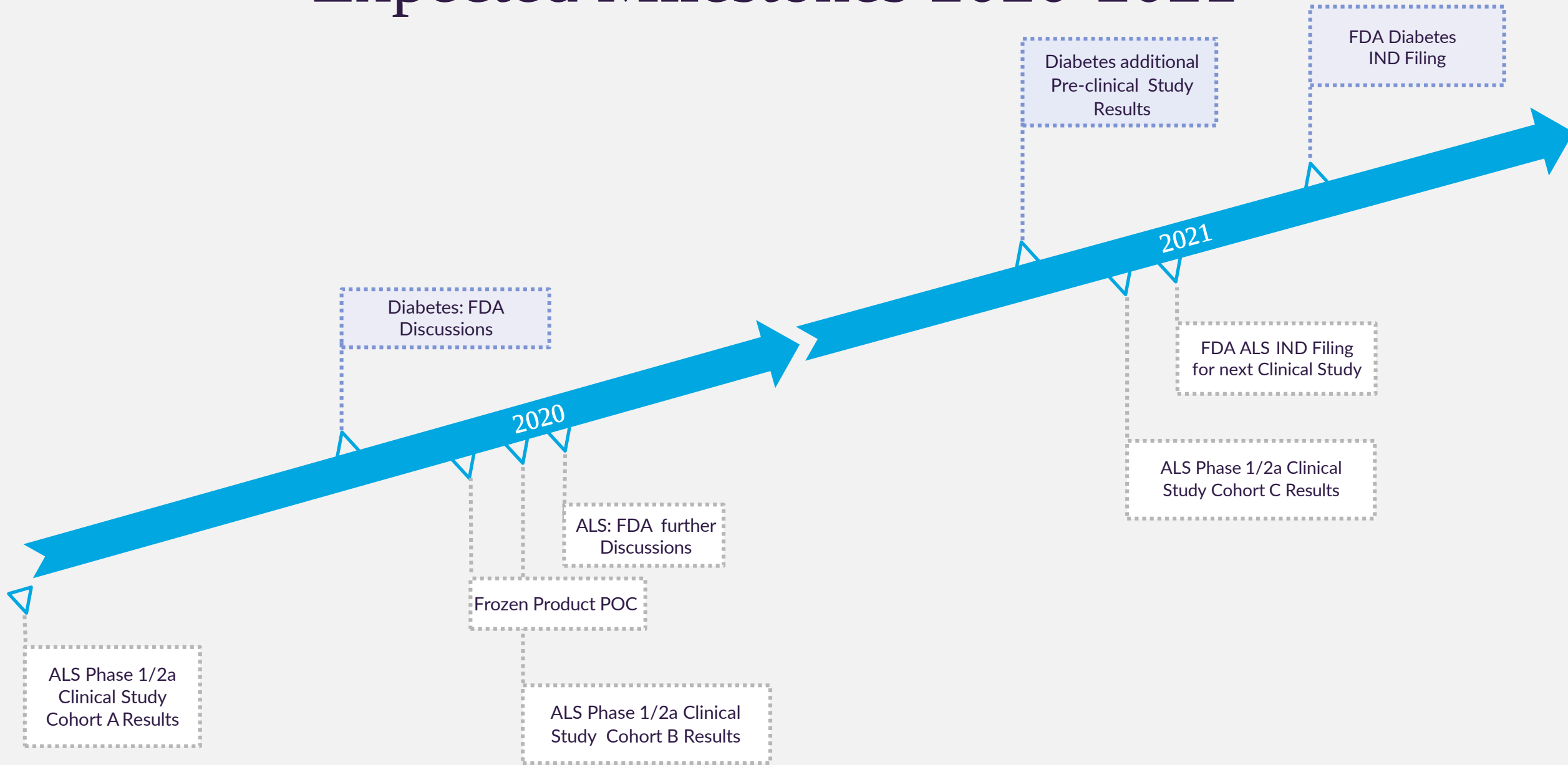


Diabetes – Insulin Dependent Treatments



	<div>KADIMASTEM</div> <div>Allogeneic Islet Transplantation</div> <div>IsletRx</div>	Insulin Injections	Islet Transplantation from Donors
One-time Treatment, Long-term Effect	✓	✗ (Daily Injection)	✓
Balanced Glucose Levels	✓	✗ (non-biological glucose sensing)	✓
Personal Comfort	✓	✗ (Daily routine interference (injections and laborious monitoring))	✓
Compliance	✓	✗ (Requires high-level treatment management)	✓
Treatment Availability	✓	✓	✗ (2-3 donors needed for 1 patient ; Less than 6,000 patients treated between 1999-2015.
Prevention of Long-term Complications	✓	✗	✗ Possible immunosuppression side effects.

Expected Milestones 2020-2021





About Us

Bringing extensive business, industry, and scientific experience.

Our Leadership

Bringing extensive business, industry, and scientific experience.



Rami Epstein
CEO

- Co-Founder, Director and COO of IDgene Pharmaceuticals Ltd.
- Co-Founder and Director of BiondVax Pharmaceuticals Ltd.
- King's College, University of London; LL.M
- The Hebrew University of Jerusalem; LL.B
- Over 25 years of business and legal counsel in the Biotech industry



Prof. Michel Revel
Founder & CSO

- Developed Merck's blockbuster drug REBIF® for multiple sclerosis (\$1.7B USD in sales in 2016)
- Professor Emeritus of molecular genetics at the Weizmann Institute of Science
- Over 40 years of experience in development and global commercialization of advanced biotechnological products

Yossi Nizhar
CFO

- Over 20 years of financial and commercial experience in the biotech and pharmaceutical industry (CFO at Genzyme, AstraZeneca Israel)
- MBA, Bar-Ilan University
- Bachelor's degree in Accounting and Economics, Tel-Aviv University, Israel
- Certified Public Accountant

Dasy Mandel
Director of Business Development

- 15 years of management, business, and regulatory experience in the medical and biotech industry
- PhD student at Vlerick Business School.
- MBA, Hult International Business School.
- B.Sc in Biotechnology Engineering, Technion

Arik Hasson, PhD
VP R&D

- 20 years of R&D experience in the biotech industry.
- PhD in cellular neurobiology, The Hebrew University of Jerusalem.
- R&D Director of the Israeli Consortium for Stem Cells R&D ("Bereshit").
- Author of tens of peer-reviewed papers in the fields of stem cells, cell therapy, neurobiology and of 17 patents.

Michal Izrael, PhD
VP R&D, NDD

- 10 years of R&D experience in the biotech industry.
- PhD in molecular genetics, The Weizmann Institute of Science.
- M.Sc. in Neurobiology, The Hebrew University of Jerusalem.

Kfir Molakandov, PhD
Head of Diabetes Research

- PhD in molecular genetics, Tel-Aviv University.
- Research Associate, Gene Therapy Center, UAB, US.
- M.Sc. in Diabetes Gene Therapy, Tel-Aviv University.
- Expert in Developmental biology.

Our Scientific Advisory Board

Cell Therapy, Neurology, and Endocrinology world renowned experts

Prof. Tamir Ben Hur

Head of Brain Division and Head department of Neurology at Hadassah University Medical Center and a world renowned expert in neurological diseases including ALS.

Prof. Joseph Itskovitz-Eldor

World renowned expert and pioneer in pluripotent stem cell research and former head of Obstetrics and Gynecology at Rambam Medical Center.

Prof. Evan Snyder

Director of the Stem Cells and Regeneration program at Sanford Burnham Prebys Medical Discovery Institute. Director, Stem Cell Research Center, UCSD.

Prof. Benjamin Reubinoff

Head of the Department of Obstetrics and Gynecology at Hadassah University Medical Center and a world renowned expert and pioneer in pluripotent stem cell research.

Prof. Jeanne Loring

Founder and director of a center for regenerative medicine in California, professor of developmental neurobiology, an expert in stem cell research and neurodegenerative diseases.

Prof. Danielle Melloul

Senior Researcher at the Endocrinology and Metabolism Center of Neurology at Hadassah University Medical Center.

Prof. Eddy Karnieli

Former Director of the Institute for Endocrinology, Diabetes and Metabolism at the Rambam Medical Center, and a world renowned expert in these fields.

Prof. Shimon Efrat

Professor of Human Molecular Genetics and Juvenile Diabetes at Tel Aviv University and a world renowned expert in cell replacement therapy for diabetes.

Thank You.

We welcome partnerships and collaborations. Please contact us:



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