

Market Overview and Business StrategyMay 2019



Forward Looking Statements

This Presentation includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking reflect management's current expectations and assumptions, as of the date of this Presentation, and involve certain risks and uncertainties. All statements other than statements of historical fact contained in this Presentation are forward-looking statements including business strategy, prospective products and technologies and objectives by the company. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors. Factors that could cause future results to differ materially from recent results or from those anticipated in these forward-looking statements include, but are not limited to, whether our reorganized CDMO operations and partnership with Great Point are successful, our ability to achieve and maintain overall profitability, the sufficiency of our working capital to realize our business plans, the anticipated growth of the market for our products and services, the development of our transdifferentiation technology as therapeutic treatment for diabetes, our technology not functioning as expected, our ability to retain key employees, our ability to satisfy the rigorous regulatory requirements for new products and procedures, our competitors potentially developing better or cheaper alternatives to our products and services, and the other risks and uncertainties discussed under the heading "Risk Factors" described in our Annual Report on Form 10-K for the year ended November 30th 2017, filed with the Securities and Exchange Commission ("SEC") on February 13, 2019 and in our subsequent periodic reports with the SEC. You are cautioned not to place undue reliance on the forward-looking-statements, which speak only as of the date of this Presentation. We do not intend, and disclaim any obligation, to revise or update any forward-looking information contained in this Presentation or with



Investment Highlights

- ✓ Cell & Gene Therapy industry growth estimated from \$26.7bn USD in 2018 to \$150bn USD in 2025*
 - Anticipated global manufacturing shortage as the cell therapy industry scales up
- ✓ <u>New point-of-care (POCare) model; establishing a global network of leading healthcare facilities to deliver autologous cell therapy products</u>
- ✓ First class customer base includes many of the leading companies in the immuno-oncology sector
- ✓ Growing therapeutic pipeline based on academic and hospital collaborations
- ✓ Rapid revenue growth and improving fundamentals [FY 2018 results]
 - Revenue increased 85% to \$18.7 million, as compared to \$10.1 million for the same period last year
 - Gross profit increased 139% to \$7.8 million, and gross margin increased to 42% versus 32.5% for the same period last year
 - CDMO segment recorded an operating profit of \$4.0 million
- ✓ Clean capital structure and solid balance sheet with approximately \$16.1 million of cash and approximately \$28.7 million of shareholders' equity (as of November 30, 2018)



Orgenesis' Vision

Providing the pathway for cell and gene therapies to cure disease, by furthering the research, development, and manufacturing of technologies throughout the world



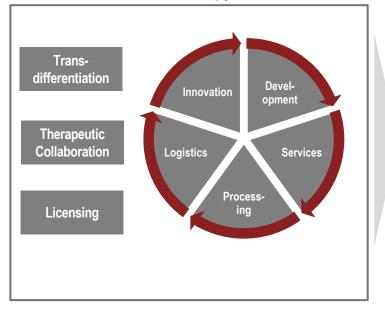
Orgenesis – Overview

An integrated service and research company within the Advanced Therapy Medicinal Products Industry focused on cell therapy development and manufacturing

Point of Care Cell Therapy Platform

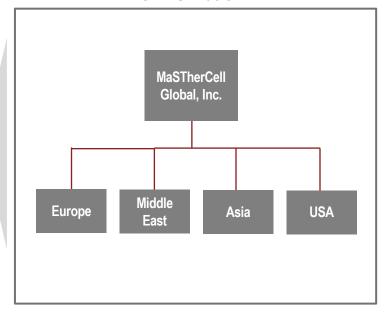
Manufacturing & development services for world's leading biopharma companies

POCare Cell Therapy Platform



Hybrid Business
Model with
Operational
Synergy Between
Platforms

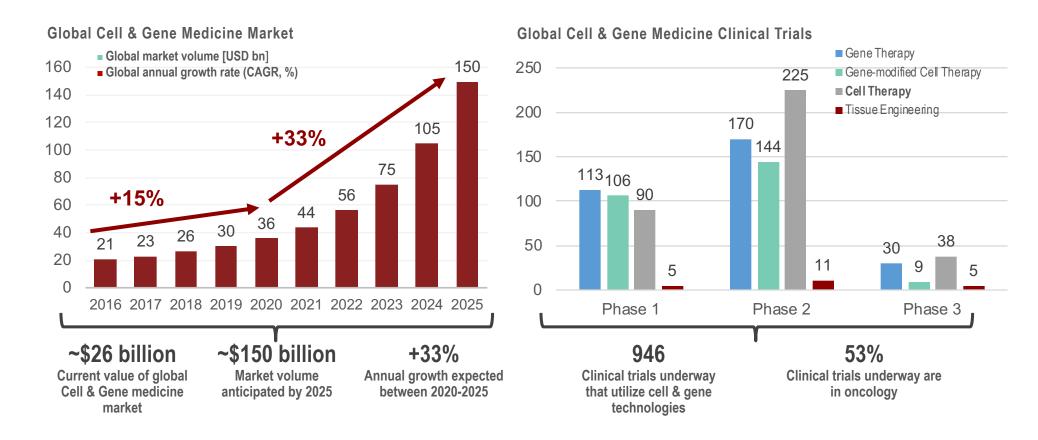
CDMO Platform





Cell & Gene Therapy Medicine Industry – Expansion

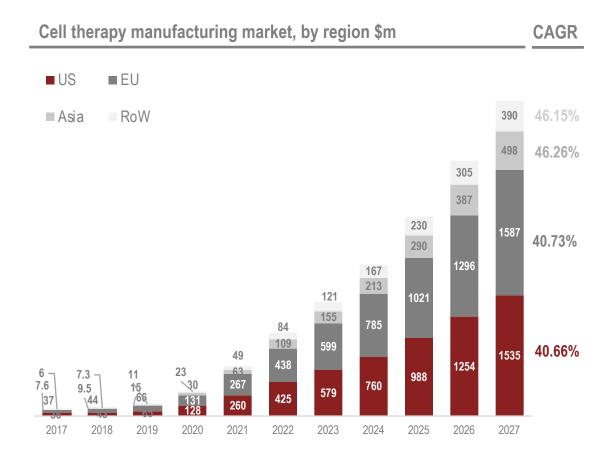
Early stage development candidates represent near-term opportunity in rapidly growing cell therapy market



Source: Roland Berger FocusCell & Gene Medicine, September 2017



Cell Therapy Manufacturing Market

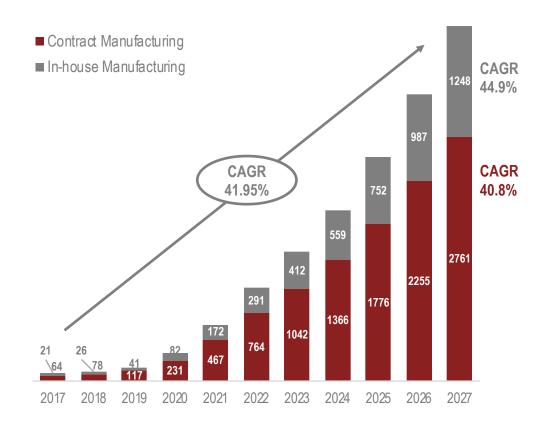


Cell Therapy Making Headlines

- Manufacturing market is estimated at \$86m in 2017 and forecasted to reach \$4bn by 2027
- FDA approved CAR-T
- Gilead acquired Kite \$11B
- Pfizer signed a deal with Allogene to develop a cancer cell therapy
- Explosive growth in VC
- NHS funding Novartis' CAR-T therapy Kymriah



Cell Therapy Manufacturing Market In-house Versus Contract Manufacturing



Remarks

- In-house manufacturing primarily performed by big pharma
- Third party manufacturers account for ~70% of total industry
- ~70% of the developers outsource their manufacturing for cell therapies



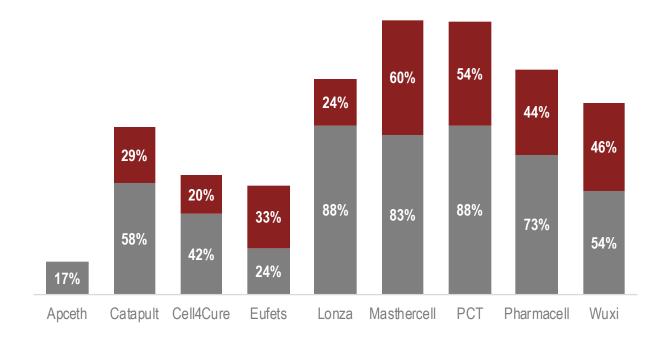
CDMO Platform: Masthercell Global

Masthercell sub is a global leader in the CDMO market: among the best known and most highly trusted CDMOs worldwide

Survey results

"Would consider collaborating with"

"Familiar with the company"



Comments

- Revenue has increased from a runrate of \$3 million in 2015, to a current run-rate of approximately \$25 million at the end of 2018
- CDMO improved analytical development and execution, including adding product characterization technology to support early and latestage development.



Source MaSTherCell brand and awareness research and survey conducted by Imagebox Communicaitons; global C-Level survey



Masthercell Global - Representative Customers

Each customer represents a potential significant revenue/growth opportunity upon regulatory approval:

- ✓ Manufacturing cost/CDMO revenues range per patient: Estimated \$10,000 – \$50,000
- ✓ Cell manufacturing profits may equal or surpass those of the drug developer



2018 new Customers

- ✓ Iovance (Phase III → MSA & PS)
- ✓ Zelluna (Development and CTM → MSA)
- ✓ Agentus (Development diagostic MSA and full development + CTM LOI)
- ✓ Kangstem (CTM LOI + MSA)
- ✓ Reneuron (Feasibility study MSA)
- ✓ GSK (Potency assay → continuity of Adaptimmune project)

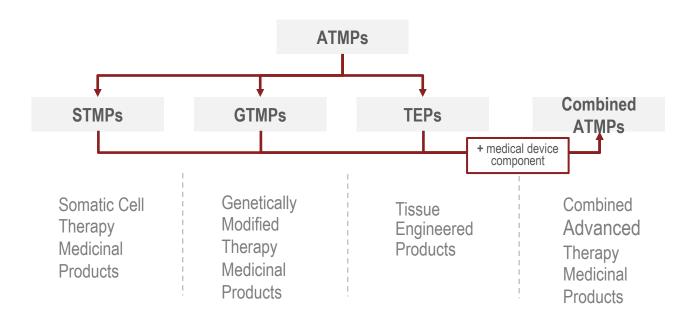








Advanced Therapy Medicinal Products (ATMPs)



Source: Roots Research Report: Cell Therapy Manufacturing Market, 2017-2027 European Medicines Agency: Advanced therapy medicinal products, 2nd international awareness session



How Do We Categorize These Therapies? Treatment / Drug





POCare Cell Therapy Platform

POCare Model: Orgenesis' Solution to Overcome Industry Challenges

Challenges

A Manufacturing technology lacking behind

No defined commercial pathway

No industrial and distribution infrastructure

Disconnect between hospitals and industry

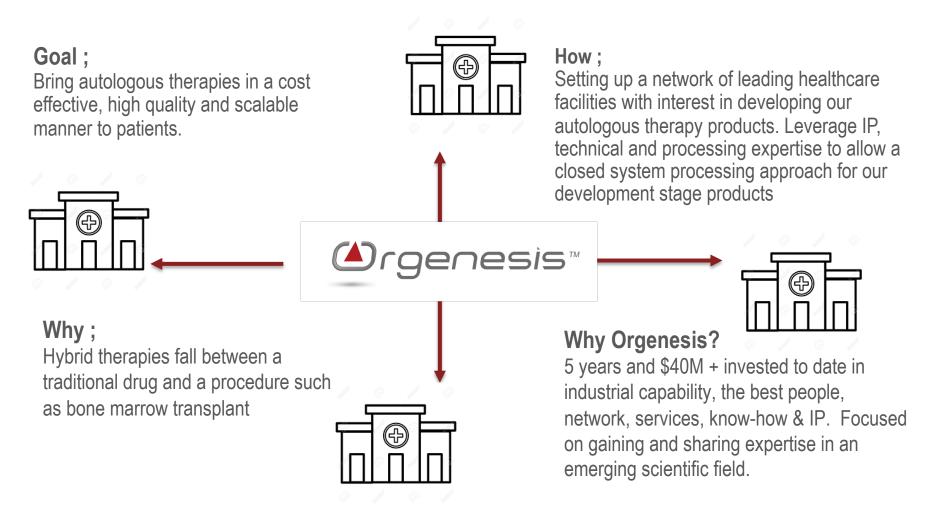
Orgenesis' solution

- Apply industrial manufacturing know-how
- Higher automation levels and closed systems
- Provide key processing components
- · Comprehensive portfolio of ATMPs
- Continuous in-licensing of autologous therapies and associated technologies
- Out-licensing hospital and academic based therapies
- Global network of "distributed" production
- Harmonized quality system across network
- Distribution and production based on point-of care
- Joint Venture ("JV") with regional partners
- Partnerships with local hospitals
- · Utilizing hospital network for clinical development of therapies



POCare Cell Therapy Platform: Hospital Based Collaboration Model

Decentralized model for ATMP development and supply





Basis for Hospital R&D Collaborations

Four Pillars of Point of Care Model

1

Unique Know-How

- Innovative Industrial processes
- · Operational excellence
- Process development and optimization
- QC assays development
- · Quality management system
- Regulatory expertise

2

Technology

- Utilizing Sensor technology & Al based systems for biological production
- Closed system devices for processing cells
- Proprietary virus/ media technologies
- Partnerships with key system providers

3

Therapies Portfolio

- Unique portfolio of immunooncology related technologies
- MSC and Liver based therapies
- · Secretome based therapies

Infrastructure /
Distribution Channels

- Installation of Point of Care systems in major hospitals
- Key geographies include: Europe, North America, Asia, South America, etc.
- Regional and international system network serve as distribution channels

Innovation

Leverage unique knowhow and expertise

Systems

Provide modular cell production cGMP systems

Cell & Gene Products

Grow internal asset pipeline

Distribution

Enable commercialization and distribution



Orgenesis Closed Production Systems

♣ Production costs

Level of automation ____



1st generation closed systems (expected Q1 2020)

The core product will be a closed POCare production system for different types of cells:

- ✓ Immune system cells NK / T / CarT
- ✓ Attached cell culture Diabetic / MSCs.
- ✓ Cell secretion Exosomes etc.

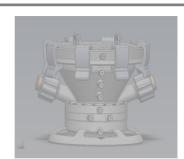
2nd generation fully automated closed systems (expected 2021)

- ✓ A modular cell manufacturing cGMP system that will enable autologous cell therapy manufacturing in an out scaled and de-centralized manner
- ✓ Allowing optimization, tight quality assurance and cost reduction
- ✓ Per patient cost can potentially be reduced to \$30,000 \$80,000

Carriers and Disposable components development

Collaboration with leading partner to designed and streamline product development path, from initial concept to design transfer and beyond;

- ✓ Carriers for Exsosomes and Adherent cells for the POC system
- ✓ Disposable bags for the electronic batch record (part of the control system)
- ✓ R&D collaboration for additional product







Implementation Plan – Cost Reduction Plan

High costs of Immuno-Onocology products of ~\$300k are considered the main obstacle for cell therapies – An efficient POCare system could lower cost to ~\$30k

Costs of conventional manufacturing vs. automated POCare production

Current market prices

Year Production costs for CAR T batch
2018 \$250,000-\$350,000

Potential costs with Orgenesis technology & processes



Rationale

Production costs

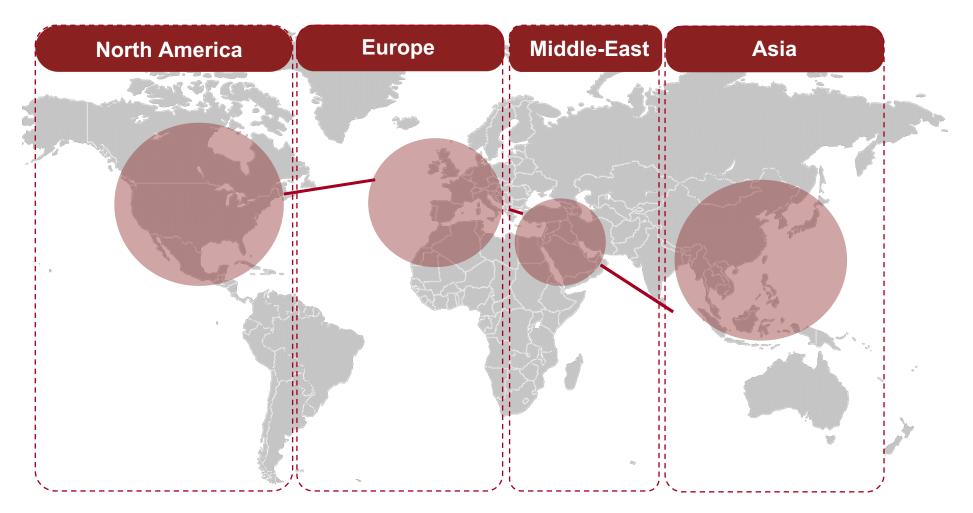
- With new and state of the art production solutions and automation the estimated cost of production of a CAR T therapy could be 84% lower than conventional manufacturing
- Cost drivers that could be significantly lowered with Orgenesis' highly efficient processes and technology for POCare cell production:
 - 1.Labor costs
 - 2.Logistics
 - 3. Quality control
 - 4.Disposables
 - 5.Cleaning costs



Automation Level

POCare Cell Therapy Platform: Global Network

Partners throughout North America, Europe, Asia and Middle East





Orgenesis Therapeutic Pipeline

Advanced Cell Therapies - Therapeutic Areas	Partner
Insulin Dependent Diabetes Liver-derived Autologous Insulin Producing Cells (AIPs)	∆ rgenesis™
Hematological Disorders Human Postnatal Hemogenic Endothelial Cells (Hu-PHECs) for Replacing Bone Marrow Transplants	HEMOGENYX PHARMACEUTICALS
Liver-Derived Metabolic Disorders HepaCell	CURE & THERAPEUTICS NEXT GENEGATION INNOVATIVE THERAPEUTICS
Cell-based Cancer Immunotherapy NK-NHP - NK cells homing protein targeting solid tumours	CURE & THERAPEUTICS
Tumor cell-based vaccine DUVAC cancer vaccine for Pancreatic, Hepatic and Cholangiocarcinoma cancers	COLUMBIA UNIVERSITY
Cell-based Cancer Immunotherapy NGMT (Non genetically modified T cells) - Colorectal cancer and Melanoma	∆ rgenesis™
Cell-based Cancer Immunotherapy CAR-T-VAC69 - Ovarian cancer and Multiple Myeloma	Caerus Therapeutics
Bioxomes for Intracellular Delivery Bioxosome and Redoxome for Liver Disorders and Atopic Dermatitis	Excellbio Ltd.



Advanced Cell Therapies - Therapeutic Areas

Autologous Insulin-Producing Cells (AIPs) ORG Ltd

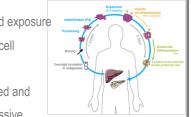
 Transforms the patient's own liver cells into fully-functional and physiologically glucose-responsive insulin-producing cells

 Overcomes the significant issues of donor shortage, cost and exposure to chronic immunosuppressive therapy associated with islet cell transplantation

 Because AIPs are autologous, this benefit should be achieved and maintained without the need for concomitant immunosuppressive therapy



- Hu-PHECs generate cancer-free, patient-matched blood stem cells
- Improves the efficacy of the therapy and potentially eliminates the challenge of finding a matching donor
- Hu-PHECs can be derived from
 - Umbilical cord and placenta
 - Patients' liver biopsies for autologous transplantations
 - Patients' livers



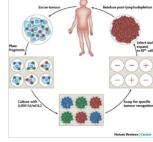
Combinatory immunotherapy NK-mAb109-NHP Cure Therapeutics

- NK cells have been identified on the basis of their ability to lyse tumor cells without prior sensitization, but transferred NK cells have poor capacity to home around solid tumor tissue
- NHP promoting NK cells are trafficked to the tumor site, improving the therapeutic effect of NK cell therapy on malignant disease
- Currently our combinatory immuno-therapy is focusing on the combination of mAb 109NHP and NK derived cell therapy for advanced gastric and colorectal cancer

D

Autologous Tumor Infiltrating Lymphocytes (TIL) ORG MD

- Solid tumor cells contain Tumor Infiltrating Lymphocytes (TILs) that recognize tumor antigens
- TILs can be expanded ex vivo by culturing them in the presence of interleukin 2 (IL-2)
- Orgenesis is developing a novel sterile flow system that enable a faster and safer culturing and expansion process
- Currently our pipeline is focusing on TILs therapy to treat Advanced
 Colorectal Cancer and Metastatic Melanoma





Advanced Cell Therapies - Novel Technologies



Automated point of care immune cells processing system

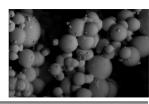
- An innovative automated end-to-end T cell manufacturing cGMP system for CAR T's, TLR's, TIL's, DC and NK cells
- The system will eventually allow full automation of the process
- Designed with a closed disposable set which will allow use outside of Grade B/C hospital clean rooms
- Dramatically the cost and complexity of cell processing





Biodegradable and Injectable cell PGS scaffold

- Development of a proprietary and first of a kind biodegradable scaffold for cell culturing of engineered poly glycerol sebacate (PGS)
- The scaffold will allow injection of the cells in their 3D structure resulting in higher viability and efficacy
- This technology will help to achieve higher yields of cells due to the high surface to volume ratio and reduce the downstream steps resulting in reduced cost of goods, improved quality and safety for the Insulin Producing Cells and other adherent cells such as MSC's





Single use sensors for Bioreactors **MIRCOD**

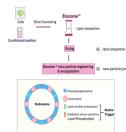
- Biological sensing with wireless charging for clinical development and manufacturing projects
- Data is monitored and recorded in real-time and stored securely for further evaluation
- A fully integrated approach for monitoring and powering the monitors ensures that there is no contamination because it maintains a closed environment and no loss of power to sensors





Bioxome and redoxome **Excellbio Ltd**

- Bioxome mimicking exosome self-assembly natural membrane enter the cell through fusion and endocytosis with the cell membrane, delivering designed target cargo
- This technology can be applied for *in-vitro* and *in-vivo* delivery platforms such as cell transfection, in-vitro toxicity assays, animal modeling, gene therapy

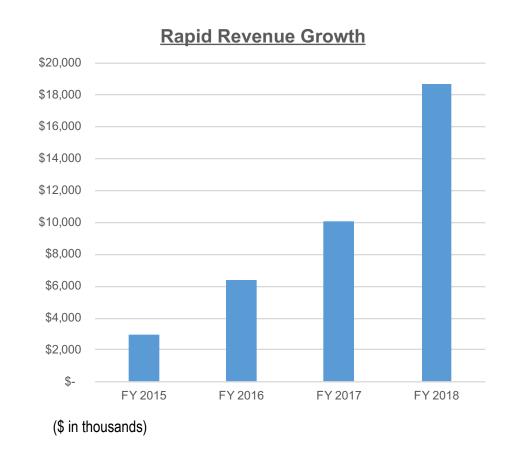




Financial Results

FY 2018 financial highlights include:

- ✓ Revenue increased 85% to \$18.7M
- ✓ Gross profit increased 139% to \$7.8M
- ✓ Gross margin increased to 42% versus 32.5% in prior year
- ✓ CDMO segment recorded an operating profit of \$4.0M
- ✓ Ended quarter with \$16.1M of cash and approximately \$28.7M of shareholders' equity





Senior Management Team

Vered Caplan - President, Chief Executive Officer and Director. Vered Caplan has been the CEO since August 14, 2014, prior to which she was Interim President and CEO since December 23, 2013. Since 2008, Ms. Caplan has been Chief Executive Officer of Kamedis Ltd., a company focused on utilizing plant extracts for dermatology purposes. From 2004 to 2007, Ms. Caplan was Chief Executive Officer of GammaCan International Inc., a company focused on the use of immunoglobulins for treatment of cancer. During the previous five years, Ms. Caplan has been a director of the following companies: Opticul Ltd., a company involved with optic based bacteria classification; Inmotion Ltd., a company involved with self-propelled disposable colonoscopies; Nehora Photonics Ltd., a company involved with moninvasive blood monitoring; Ocure Ltd., a company involved with wound management; Eve Medical Ltd., a company involved with prostate cancer diagnostics. Ms. Caplan has a M.Sc. in biomedical engineering from TelAviv University specializing in signal processing; management for engineers from TelAviv University specializing in business development; and a B.Sc. in mechanical engineering from the Technion-Israel Institute of Technology specialized in software and cad systems.

Neil Reithinger, CPA - Chief Financial Officer, Secretary, and Treasurer. Neil Reithinger was appointed Chief Financial Officer, Secretary and Treasurer on August 1, 2014. Mr. Reithinger is the Founder and President of Eventus Advisory Group, LLC, a private, CFO-services firm incorporated in Arizona, which specializes in capital advisory and SEC compliance for publicly-traded and emerging growth companies. He is also the President of Eventus Consulting, P.C., a registered CPA firm in Arizona. Prior to forming Eventus, Mr. Reithinger was COO & CFO from March 2009 to December 2009 of New Leaf Brands, Inc., a branded beverage company, CEO of Nutritional Specialties, Inc. from April 2007 to October 2009, a nationally distributed nutritional supplement company that was acquired by Nutraceutical International, Inc., Chairman, CEO, President and director of Baywood International, Inc. from January 1998 to March 2009, a publicly-traded nutraceutical company and Controller of Baywood International, Inc. from December 1994 to January 1998. Mr. Reithinger earned a B.S. in Accounting from the University of Arizona and is a Certified Public Accountant. He is a Member of the American Institute of Certified Public Accountants and the Arizona Society of Certified Public Accountants.

Sarah Ferber Ph.D. - Chief Scientific Officer. Prof. Sarah Ferber was appointed Chief Scientific Officer on February 2, 2012. Prof. Ferber studied biochemistry at the Technion under the supervision of Professor Avram Hershko and Professor Aharon Ciechanover, winners of the Nobel Prize in Chemistry in 2004. Most of the research was conducted in Prof. Ferber's Endocrine Research Lab. Prof. Sarah Ferber received TEVA, LINDNER, RUBIN and WOLFSON awards for this research. Prof. Ferber's research work has been funded over the past 15 years by the JDRF, the Israel Academy of Science foundation (ISF), BIODISC and DCure.



Senior Management Team (cont.)

Dr. Ohad Karnieli (PhD, MBA) – General Manager

Dr Karnieli is the founder of Atvio Biotech, a specialty cell and gene therapy automation and process development firm, part of the MaSTherCell global network. Dr. Karnieli earned his PhD in Biotechnology focusing on Cell & Gene Therapy from the Sacler school of Medicine at Tel Aviv University and an MBA from the Haifa University school of management. Dr. Karnieli served in several executive rolls in the field of cell therapy and medical devices with his last position being the VP of Technology & Manufacturing at Pluristem Therapeutics. A well-known expert in the field of cell therapy process development and serves on several industry committees including chairing of the process & product development committee of the International Society for Cell Therapy and an expert member in the ISO TC276 Bioprocessing committee.

Dr. Shimon Hassin – Chief Technology Officer

Dr. Shimon Hassin has over 20 years of experience in Biotechnology, with specific expertise in the development of biopharmaceuticals. Prior to joining the company, Dr. Hassin was co-founder and CEO of Kadimastem, an embryonic stem cell company developing an artificial pancreas for curing Juvenile Diabetes. Before joining BiondVax, he worked at InSight Biopharmaceuticals, a leading Israeli biotechnology company active in the area of Biogenerics. In his capacity as Head of Process Development he was responsible for the manufacturing of a variety of Biogenerics such as therapeutic antibodies, cytokines and hormones. Dr. Hassin holds a Ph.D. in Biotechnology from the University of Maryland Biotechnology Institute and was a post-doctoral associate at the University of Bergen Center of Marine Biotechnology.



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Thank You

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