

Orgenesis (NASDAQ/ORGS)

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BUY Manufacturing Living Therapies

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Orgenesis is a leader in cell and gene manufacturing that is poised to capitalize on the regenerative, immuno-oncology, and stem cell markets as they rapidly grow.

Investment Highlights

We are initiating coverage on Orgenesis with a Buy rating and a \$10.00 price target. The Masthercell Global subsidiary is a vertically integrated profitable contract development and manufacturing organization (CDMO). This business is focused on support services, process innovation and technology innovation to assist customers from pre-clinical stages through commercialization developing cell and gene-based approaches to treat diseases. Masthercell is profitable with sales of \$10M in FY17 and we estimate growing to \$21M in FY18, and to \$45M in FY19 as additional capacity at the Belgium plant has been completed.

Masthercell Global can optimize manufacturing of all types of cells including immunotherapies CAR-T & TCR, dendritic cells, master stem cells (MSC) and others. Customers include CRISPER, Adaptimmune and Servier. The living drugs face many unique challenges: 1) they cannot be sterilized and need clean rooms to prepare; 2) as personalized therapy they are made in small batches with variability in yields; and 3) unique regulatory pathways and initial manufacturing costs are high. Nevertheless, efficacy rates are high in patients with no other options.

The first indication for Orgenesis' unique cell-based therapy (CT) is for the development of Autologous Insulin Producing (AIP) cells that transform the patient's own liver cell into a fully functional and physiologically glucose-responsive insulin-producing cell, designed to provide long-term insulin independence. The first indication the treatment of severe diabetes following Total Pancreatectomy (TP), which is an orphan drug indication. This trans-differentiation process that can re-program a patients' mature cells into different types of cells that have potential application across hundreds of diseases.

The next important events include: 1) expansion into Korea and the U.S. that are likely to double Masthercell Global revenues; 2) additional hospital and academic partnerships; 3) AIP I+-ND filing.

Our price target of \$10.00 is based on average of a 40x multiple of 2028 EPS of \$1.57 EPS discounted back at 25% and a 12.0x multiple of 2026 adjusted revenue of \$214M discounted back at 25%.

Risks include the usual challenges in development: 1) failure to show benefit in the clinical trial; 2) regulatory approvals; 3) the need for additional capital; 4) competing products; 5) dependence on partners; 6) reimbursement; 7) intellectual property; and 8) manufacturing.

Current Price \$4.76
Price Target \$10.00

Estimates	F2017A	F2018E	F2019E
Revenue(\$000s)	\$10.1	\$20.9 E	\$45.5 E
1Q February	1.9	\$ 2.64 A	\$9.5
2Q May	2.3	\$ 3.99 A	\$10.5
3Q August	2.6	\$ 6.23 A	\$12.0
4Q November	3.4	\$ 8.00 E	\$13.5
EPS	(\$1.47) A	(\$0.88) E	(\$0.45) E
1Q February	(0.66)	(0.08) A	(0.14)
2Q May	(0.26)	(0.20) A	(0.11)
3Q August	(0.38)	(0.35) A	(0.11)
4Q November	(0.17)	(0.25)	(0.09)
P/E (x)	N/A	N/A	N/A
EBITDA/Share	\$0.00	\$0.00	\$0.00
EV/EBITDA (x)	0.0	0.0	0.0
Stock Data			
52-Week Range	\$4.11 - \$16.80		
Shares Outstanding (mil.)	15.6		
Market Capitalization (mil.)	\$74.1		
Enterprise Value (mil.)	\$59.8		
Debt to Capital	8.7%		
Book Value/Share	\$2.18		
Price/Book	2.2 X		
Average Trading Volume (3-month) Mill	0.1		
Insider Ownership	20.4%		
Institutional Ownership	1.8%		
Short interest	1.8%		
Dividend / Yield	\$0.00 - 0.0%		



Price target and ratings changes over the past 3 years:
 Initiation - December 20, 2018 - Buy - Price Target \$10.00

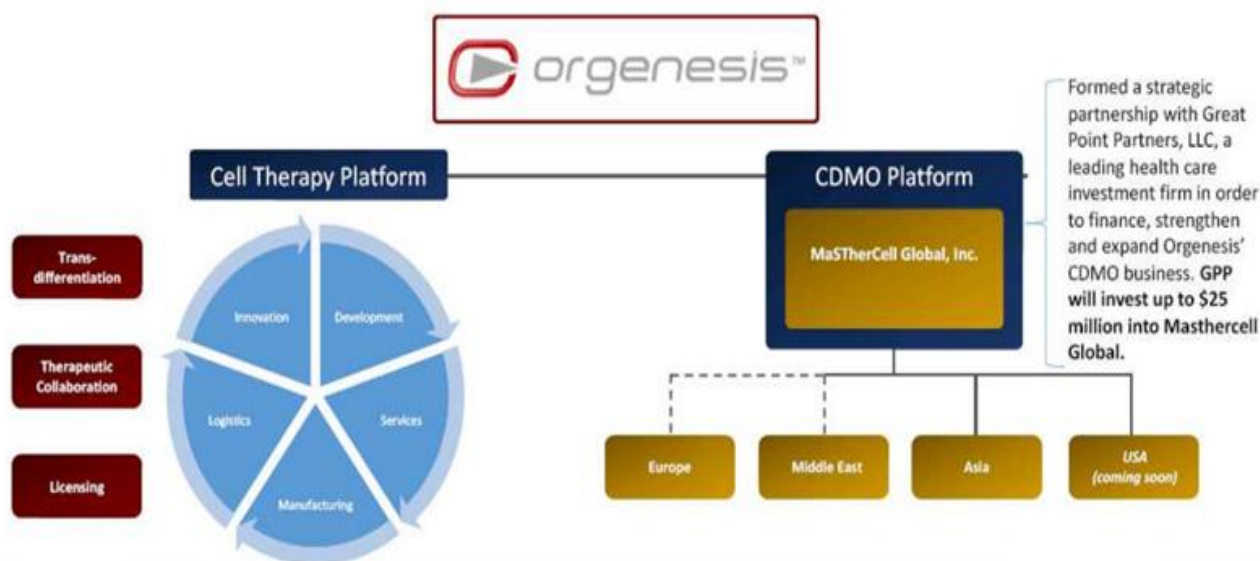


Company Overview

Orgenesis was founded in 2010 by Doctor Sarah Ferber, head of endocrine research at Sheba Medical Center and is a Nevada corporation. This biotechnology company has expertise and experience in cell therapy development, including manufacturing specializing for advanced medicinal products produced by the cell therapy industry. Orgenesis is also developing a trans-differentiation technology for the treatment of diabetes and other diseases. The trans differentiationCell Therapy (CT) technology is based on the research work of Sarah Ferber, the Company's Chief Science Officer (CSO). In preclinical studies proof of concept has been established showing an adult liver cell can be converted into “pancreatic beta cell-like” insulin-producing cells.

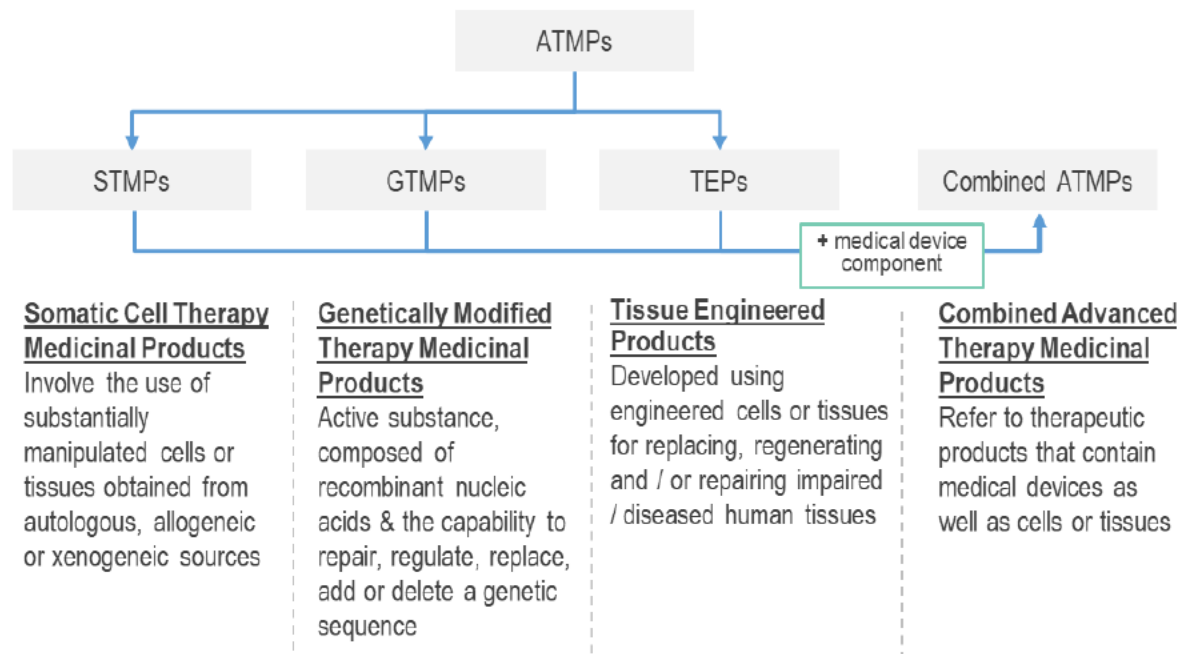
The company has two related subsidiaries. Masthercell Global, formerly MasSTerCell S.A, which is a global Contract Development and Manufacturing Organization (CDMO) based in Belgium, Israel and Korea, and expanding into the US. The CDMO business is cash flow positive and provides funds for the propriety CT Platform. The initial target is Total Pancreatectomy (TP), a condition by which patients become brittle diabetics, this therapy may also apply to insulin dependent diabetes.

Exhibit 1. A Dual Business Model



Source: Company reports.

Orgenesis has built a platform of know-how and expertise for a multitude of cell therapies, including autoimmune, oncologic, neurologic and metabolic diseases and other indications. Orgenesis provides services for leading pharmaceutical and biotech companies as well as research institutions and hospitals that have cell therapies in clinical development. Each of these collaborators represents a significant revenue and growth opportunity upon regulatory approval.

Exhibit 2. Advanced Therapy Medicinal Products (ATMPs)


Source: Company reports.

STMPs and GTMPs dominate the market right now and are attracting the highest investment. In the future, in order to access the market potential and trends other cell products are likely to be essential in all these categories.

Orgenesis is just beginning rapid growth supplying and ultimately may commercialize therapeutic cell and gene therapy products. The timing is just right, and the company is in the right place after years of investment. Live cell manufacturing is unlike any other therapeutic categories, and Orgenesis is the leader, in our opinion. Orgenesis has the capabilities to assist companies to overcome the current changes in the industry which include: 1) few CDMOs and even less with global reach; 2) high cost and inability to scale efficiently; 3) insufficient industry capacity; 4) low product quality (yield); and 5) lack of expertise and knowledge.

Exhibit 3. Orgenesis' Milestones

Milestone	Timing
Masthercell signs additional company partnerships	ongoing
Orgenesis signs additional hospital partnerships	ongoing
Open Texas contract development and manufacturing service center	ongoing
Korea up and running	ongoing
IND for AIP cells for total pancreatectomy	2019
Japan up and running	2019
Establish factories in Germany, Greece and other research partnerships	2019
CDMO 1st generation closed systems	1Q:20
DCMO 2nd generation fully automated closed systems	2021
Potential launch of AIP cells	2024

Source: Company reports, Dawson James Securities research.



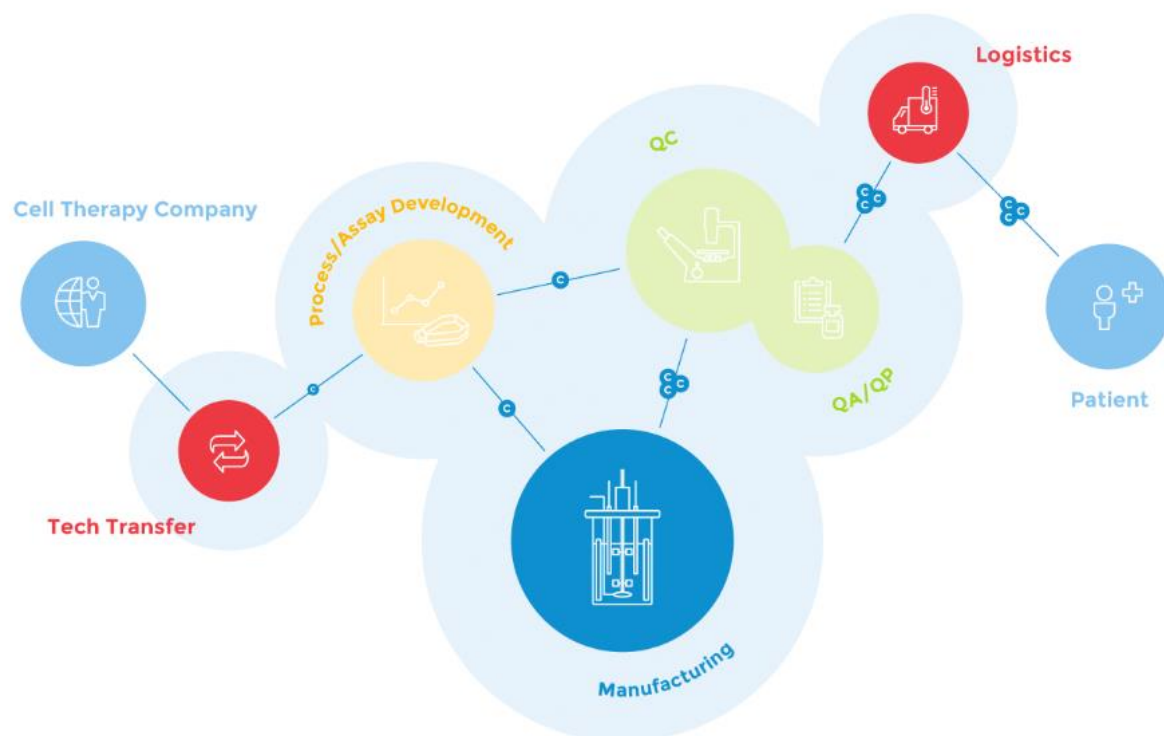
Part 1: Masthercell Global the CDMO Platform

One of the major issues with moving cell therapy products from “bench to manufacturing bedside” has been manufacturing bottlenecks. The heterogeneous nature of cell therapy products has introduced manufacturing complexity and regulatory concerns, as well as scale-up complexities that are not present within traditional biologic or pharmaceutical manufacturing. Many companies developing autologous cell therapies envision using multiple manufacturing sites and processing centers to distribute the workload and minimize the shipping distances for such time sensitive products. Many cell therapy products are fragile preparations that must be shipped and administered to the patient rapidly. This time pressure means that standard product release testing procedures are not feasible. Sterility testing often cannot be completed before patient treatment. This unique challenge in cell-therapy manufacturing requires tighter environmental and handling controls to greatly reduce any risk of sterility failure. Masthercell continues to invest resources to maintain best practices in quality service, quality control, quality assurance and permanent staff training to uphold the highest standards.

Orgenesis offers the following services to its clients:

- **A more efficient path to commercialization.** Masthercell can provide manufacturing capability from pre-clinical testing to commercialization which allows for the simplest process and lowest COGS.

Exhibit 4. Masthercell Global Delivers a “One-Stop-Shop”



Source: Company reports.

- **Top Quality Control (QC) compliant with GMP requirements.** ORGS’s service transforms the client’s cell-based therapies into a robust and scalable process. Its stringent quality system is applied



throughout the process and ensures identity, purity, stability, potency and robustness of cell therapy products.

- **Academic manufacturing transformed into a standardized clinical product.** Masthercell services include examining the clinical efficiency of the laboratory product with its global academic partners and converting it into a clinical manufacturing program to support all phases of clinical trials.
- **Access to a global manufacturing network.** Companies must plan for success and tackle the logistics to treat a patient at the point of care. Therefore, a global CDMO meets this requirement and is the strategy behind the 3 CDMO facilities in Belgium, Korea and Israel, and the expansion into the US and Singapore. To comply with anticipated regulatory harmonization requirements, The Quality and Management Systems (QMS) are structured to be shared with either affiliated companies or business partners, and even with customers or prospects.
- **Central continental locations to problem solve key logistics challenges.** The company provides a team of dedicated experts both from academic and industry backgrounds with a strong experience in cGMP dealing with not yet harmonized regulatory requirements (EMEA, FDA). Also supplied are state-of-the-art facilities located next to airports (soon to be on four continents) to deal with therapies' administration at or nearby points of care, as many cell therapy products have a short shelf-life.
- **Providing additional manufacturing capacity.** One of the biggest challenges is developing reliable (quality) and robust manufacturing processes for cell-based therapy products that ensure adequate product safety, potency, and consistency at an economically viable cost. Manufacturing quality and comparability is at the heart of biotechnology companies' challenges. Masthercell has built-up a strong expertise to customize the production and manufacturing process to suit the client needs, which can facilitate a long-term revenue generating relationship.



Orgenesis to Capitalize on the Cell and Gene Therapy Multi-Billion Dollar Market

One of the promises of regenerative medicine is to replace or regenerate living human cells, tissues or organs to restore normal function. Regenerative medicine includes the possibility of growing tissues and organs in the laboratory and implanting them when the body cannot heal itself. If a regenerated organ's cells would be derived from the patient's own tissue or cells (autologous), this would potentially solve the problem of the shortage of organs for donation and the problem of organ transplant rejection,

In the last decade, cell therapy and regenerative medicine products have gained significant importance, particularly in the fields of ex-vivo gene therapy and immunotherapy (IO). While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient as the sector is new and most development has not been automated.

The U.S. Department of Health and Human Services has called it the next evolution of medical treatments: “With its potential to heal, this new field of science is expected to revolutionize healthcare”. ORGS has built a unique and fundamental base platform of know-how and expertise for manufacturing a multitude of cell types and for the regenerative medicine industry.

Cell therapy is really exciting in that it may have larger therapeutic effect than biologic agents since it is based on augmenting, repairing, replacing or regenerating organs and tissues thereby leveraging the human body’s capacity to heal. It took 20 years to get monoclonal antibodies, RNAi, and gene therapy to become viable therapies. Along the way manufacturing technologies had to catch up.

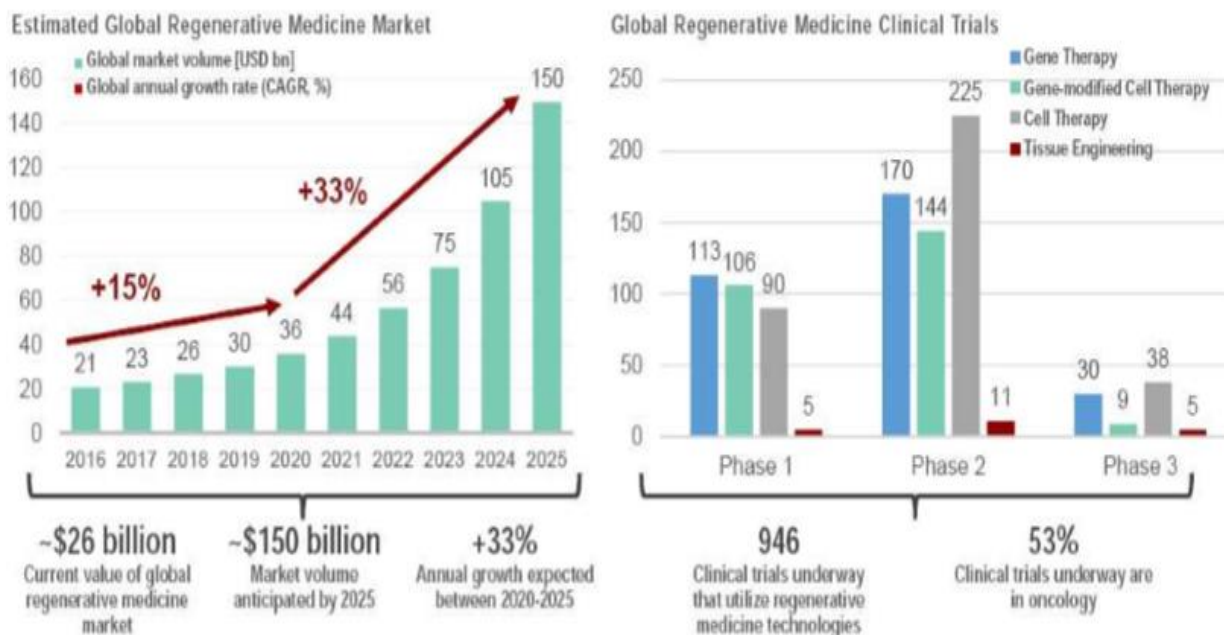
Orgenesis’ target market includes the cell therapy manufacturing market, estimated to be a \$86M in 2017 and expected to reach \$4B in 2027. Cell therapy is the prevention or treatment of human disease by the administration of cells that have been selected, multiplied and manipulated outside the body (ex-vivo). To date, the most common type of cell therapy has been the replacement of mature, functioning cells through blood and platelet transfusions. Several of these cell therapies are now standard of practice world-wide and are typically reimbursed by insurance. A prime example is bone marrow transplants and now CAR-T therapies. There needs to be manufacturing capacity to meet this demand.

The regenerative medicine market is already a \$26B market growing at 15% through 2020, and over 33+% CAGR from 2020 through 2025. Due to the differing definitions of regenerative, cell and gene therapy, the reports are hard to quantify. The market is global, with North America expected to dominate and growing rapidly, followed by the EU and Asia. Factors driving demand include the adoption of stem cell technology, growing prevalence of chronic diseases, and emerging applications of gene therapy in regenerative medicine. Regulatory and ethical issues pertaining to stem cells, tissue engineering, and regenerative medicine are a restraint for the market, as is the high cost of treatments and the accessibility to healthcare facilities in the region



Exhibit 5. Growth Estimates for the Cell and Gene Therapy Market

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



Source: Company reports.

Positive regulatory environment. Within the last year the FDA has approved 3 live cell therapies to treat certain cancers and an inherited ocular disease. These programs were granted priority review and break through status. In May, Commissioner Scott Gottlieb said the FDA will soon be alerting companies that certain gene therapies in development can qualify for less arduous review at the agency. Gottlieb said that hemophilia is the first disease the FDA will target with its new policy. An FDA spokesperson later said hemophilia was chosen because “it’s an area of a lot of development activity.” Also speeding the process is the number of patients needed to study is small, often 100 patients or less, and Phase 2 studies are enough for approval.

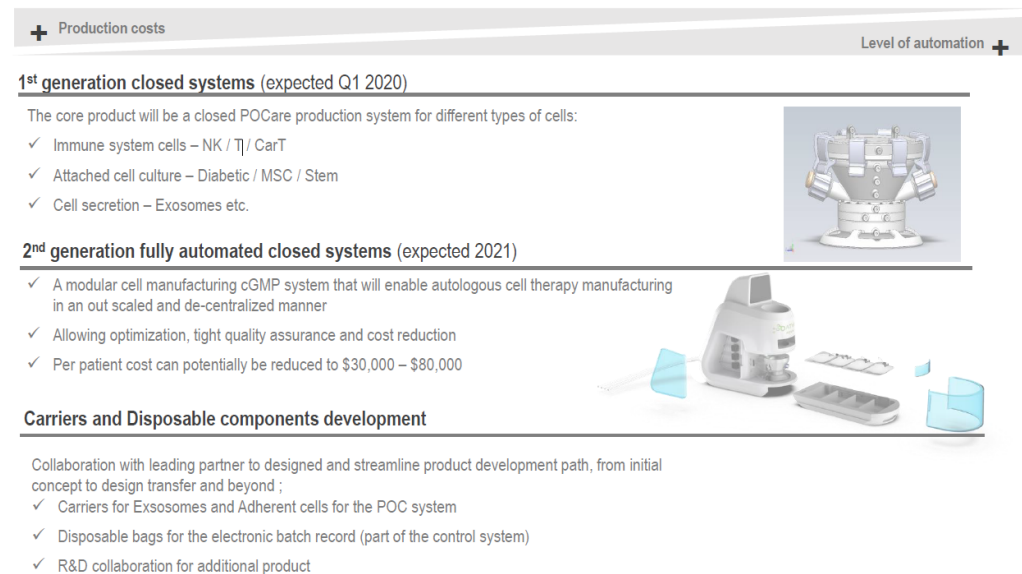
Economics is important. The FDA has approved 16 cellular therapies and the EMEA 10. None have been a commercial success until now. One with high expectations was withdrawn from the market. UniQure’s Glybera was a single \$1.4M treatment for a rare disorder called lipoprotein lipase deficiency (LPLD) and sold one vial. Approved in 2015 in the EU; it is now off the market.

Logistics is key. Dendreon’s PROVENGE was an autologous product for prostate cancer that had difficulty delivering its product nationwide from several plants in part due to the drug had to be administered within 1-2 days after production.

Autologous therapy is not viable without local automation. That was one of the major factors why Dendreon (bought by Valent) was not successful. Currently the manufacturing is done in clean rooms, that are costly.



Exhibit 6. Bedside Examples



Source: Company reports.

If successful, in our opinion, the cell therapy platform has the potential to have major impact on diseases and is much larger than the CDMO business that provides funds now. If the company can convert its CDMO model from \$1-2M tech transfer into a royalty, Orgenesis may collect royalties from the sales of many cellular therapies whether or not Orgenesis's manufacturing process is used.

The strategy for autologous therapies has been to have arrangements with local partners in international countries beyond Israel, Belgium, Korea, and the US. Orgenesis has been working directly with hospitals and strategic groups to build relationships with hospitals that are currently or planning to supply on-site manufacturing of therapeutics products that are either clinical stage trials or commercialization.

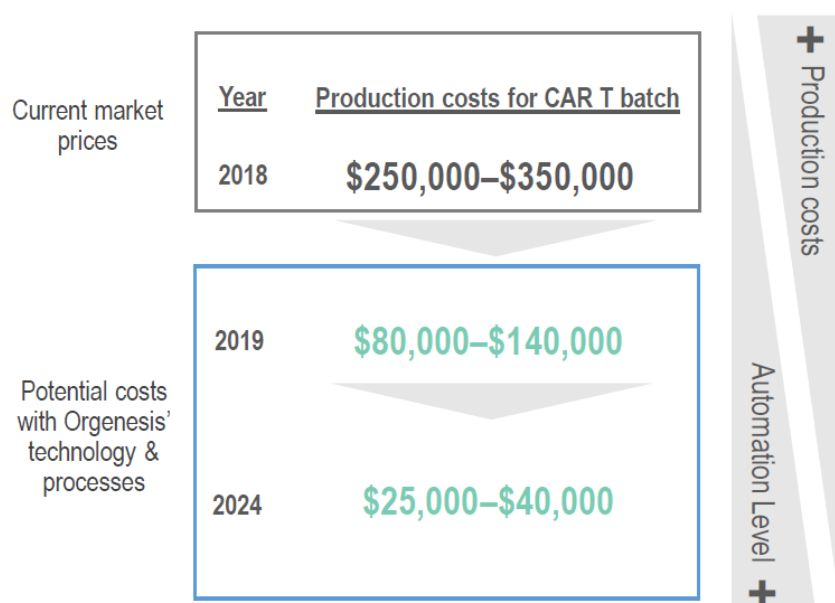
Orgenesis uses a custom-made approach, that is tailored to the specific requirements of clients and designed to ensure short lead times and competitive costs in getting products to the market. The company has employees that have expertise from both academic and industry backgrounds. A complete range of services - the advanced Project Management Program allows Orgenesis to offer a centrally managed service that covers every step of the process 'from bench to market'. Masthercell's customers include leading pharmaceutical and biotech companies, Orgenesis is partnering with research institutions and hospitals involved in cutting edge cell therapy.



Industrial Competition

We are unaware of any direct competition and believe that Orgenesis is in the lead with localized automation. Currently, big pharma has mainly internal manufacturing. Although third party manufacturers account for ~70% of the industry, both in-house and contract manufacturing is expected to grow 45% and 41% CAGR 2017 through 2027, respectively. However, the costs are very high for CAR-T therapies currently.

Exhibit 7. ORGS Estimates of Price Reduction for CAR-T



Source: company reports.

Our understanding as with other recombinant biologic breakthrough therapies, i.e. hormones and monoclonal antibodies, the companies had internal manufacturing processes. Often these have not been the most efficient methods because it has required new technology.

Other CMOs and CDMOs companies include: Lonza Group Ltd, Progenitor Cell Therapy (PCT) LLC (acquired by Hitachi), Pharmacell BV (acquired by Lonza), WuxiAppTec (WuXi PharmaTech (Cayman) Inc.), Cognate Bioservices Inc., Apceth GmbH & Co. KG, Eufets GmbH, Fraunhofer Gesellschaft, Cellforcure SASU, Cell Therapy Catapult Limited and Molmed S.p.A.



Masthercell's services are different in 2 important ways:

- 1) Quality and expertise of its services: clients identify the excellence of its facility, quality system, and people as a major differentiating point compared to competitors.
- 2) Flexible and tailored approach: Masthercell's philosophy is to build a true partnership with its clients and adapt itself to the clients' needs, which entails no "off-the-shelf process" nor in-house technology platform, but a dedicated person in the plant (of client), joint steering committees on each project and dedicated project managers.

Many of the current employees are working on the industrial product of quality control. Specifically, Orgenesis takes the living product and breaks it up and develops validated assays and characterizes the product. As the company has become more experienced, the yields have increased from 70% to over 90%. The company estimates that without introducing a more industrial process batch yields may be as low as 60% which results in a much more expensive product.

The field is in the early days of perfecting cell and gene manufacturing. The automated point of care system (POCare) should lower costs. Orgenesis estimates that manufacturing of CAR-T therapy could be 84% lower than conventional manufacturing. This is through reduced labor costs, logistics, quality control, disposable and cleaning costs.

Exhibit 8. Orgenesis's Point of Care Solutions for Cell and Gene Therapies

Challenges	Orgenesis' solution
1 Manufacturing technology lacking behind	<ul style="list-style-type: none"> • Apply industrial manufacturing know-how – Biological assay development validation and optimization • Higher automation levels resulting in significantly lower cell production costs • Provide ingredients (assays, viruses, etc.) and technology components (e.g. sensors) • Manufacturing automation enabling a closed loop system
2 No defined commercial pathway	<ul style="list-style-type: none"> • Provide hospitals comprehensive portfolio of advanced therapy medicinal products ("ATMPs") • Continuous in-licensing of autologous therapies from academia and research institutes • Out-licensing hospital and academic based therapies
3 No industrial and distribution infrastructure	<ul style="list-style-type: none"> • Global network of decentralized production • Harmonized quality system • Distribution and production based on point-of care
4 Disconnect between hospitals and industry	<ul style="list-style-type: none"> • Joint Venture ("JV") with local partners who bring strong regional networks • Through the JV - partnerships with local hospitals • Utilizing hospital network for clinical development of therapies

Source: Company reports.

Part 2: Cell Therapy (CT) Platform: an example Autologous Insulin Producing (AIP) Cells

Orgenesis has the CT platform to license technologies and launch through partnerships, which leverages the companies' manufacturing, distribution, logistic and regulatory expertise. Trans-differentiation, or cell reprogramming, is the conversion of one adult tissue/or cell into another type of cell, with its distinct phenotype and function. The cell no longer has its original function and now has a new cell function. The transition is fast and only takes a few days.

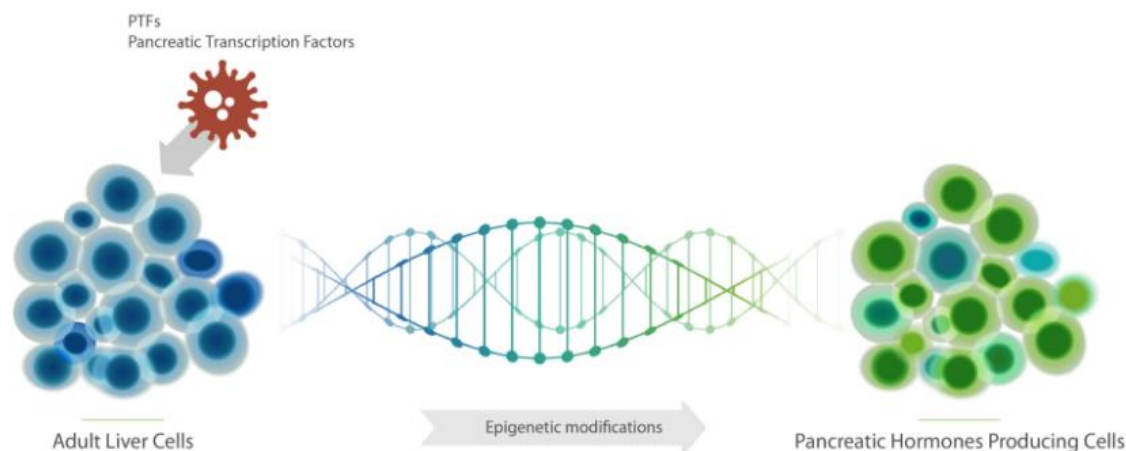
Although many types of cells could be changed, liver and pancreatic cells share a common developmental origin making liver cells good candidates for trans-differentiation into β -like pancreatic cells. Other areas of interest are cells in oncology, cardiovascular, muscle skeletal, dermatology, immunology and inflammation, gastroenterology and hematology.

During the process of trans-differentiation, the host cell acquires mesenchymal characteristics and a high level of cellular plasticity that enables it to change its original phenotype into another type of cell. For this to occur epigenetic changes are required. These epigenetic modifications can be induced artificially through the introduction of transcription factors (TFs) also called exogenous factors. The exogenous TFs serve as a 'short term trigger', which activates the expression of 'silent' relevant endogenous TFs in the treated cells, which induce comprehensive cell reprogramming. It is a safe process since the activation of the lineage specific TFs does not require the insertion of foreign genes into the genomic host. Therefore, it reduces the risk of cell mutation and allows for the testing of cells ex-vivo before administration.

The cells are changed through epigenetic manipulation which can turn genes on or off. Epigenetics explains how DNA is packed into the cell and with which chemicals it is packed. The result of this packing regulates which genes are expressed, the degree of expression, and which proteins are made. Each time a cell divides, it is subject to new packing arrangements. Each cell is different and each cell packs in concert with every other cell; each doing its part. Through epigenetics Orgenesis can manipulate cells to treat diseases.

There are several special aspects of this technology: 1) it reduces the risk of cell mutation and allows for the testing of cells ex-vivo before administration to the patient; 2) adult cells do not grow inside the patients which eliminates the risk of cancer; and 3) by using the patient's cells and not encapsulation the risk of immune response or rejection is reduced.

Exhibit 9. Autologous Trans-differentiation



Source: Company reports.



Although data is scarce, by some estimates the incidence of chronic pancreatitis ranges from 4 to 14 per 100,000 person-years, and the prevalence ranges from 26.4 to 52 per 100,000. Moreover, a meta-analysis found that acute pancreatitis progresses to chronic pancreatitis in 10% of patients who have a first episode of acute pancreatitis and in 36% who have recurrent episodes.

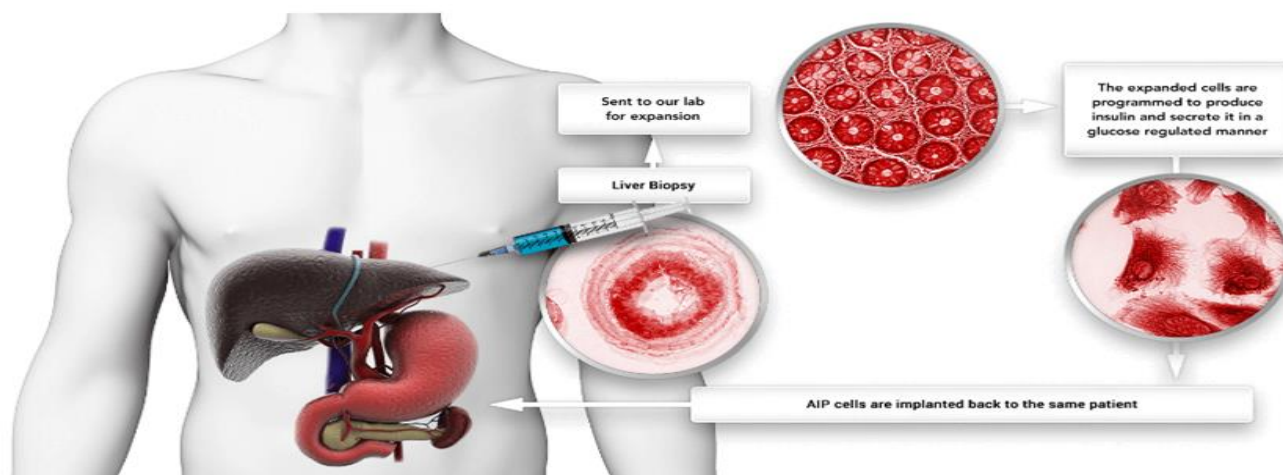
The incidence of diabetes following TP is 100%. Other potential indications include cancer, cystic fibrosis, hemochromatosis, fibro calculous pancreatopathy, and Type 1 Diabetes (T1D) and where patients are insulin dependent. The immune system destroys the β -cells in the pancreas that produce insulin that controls blood sugar. Orgenesis's treatment may transform liver cells into insulin-producing cells which would stop the need for a daily insulin treatment. This treatment may also be helpful in Type 2 diabetes (T2D), where some patients also required daily insulin.

Orgenesis is conducting additional preclinical safety and efficacy studies with in diabetic animals and other potential indications prior to initiating clinical trials. This treatment ameliorates hyperglycemia and maintains a stable body weight in diabetic mice.

The Procedure to Receive (AIP) Cells

- 1) Patient arrives to an out-patient clinic for a standard liver biopsy procedure and is sent home the same day.
- 2) The biopsy is then delivered to Orgenesis' core lab where a part of the biopsy is bio- banked and the remainder is used for producing AIP cells. This can take 4 to 5 weeks.
- 3) The AIP cells solution, packaged in an infusion bag, is delivered back to the clinic.
- 4) Patient arrives to the out-patient clinic for the transplantation procedure, which is essentially like a pancreatic islet transplantation (IV transfusion). The patient is sent home the same day.
- 5) AIP cells become effective within a few days.

Exhibit 10. AIP Treatment Procedure



Source: Company reports



Management

Vered Caplan - *Chairman of the Board of Directors, CEO and President.* Ms. Caplan has been the Chairman of the Board of Directors and CEO since August 14, 2014, prior to which she was Interim President and CEO since December 23, 2013. Since 2008, Ms. Caplan has been CEO of Kamedis Ltd., a company focused on utilizing plant extracts for dermatology purposes. Ms. Caplan has a M.Sc. in biomedical engineering from Tel Aviv University specializing in signal processing as well as a B.Sc. in mechanical engineering from the Technion-Israel Institute of Technology specialized in software and cad systems.

Neil Reithinger - *CFO, Secretary and Treasurer.* Mr. Reithinger was appointed CFO, 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. Reithinger earned a B.S. in Accounting from the University of Arizona and is a CPA. He is a Member of the American Institute of CPAs and the Arizona Society of Certified Public Accountants.

Professor Sarah Ferber – *Chief Scientific Officer.* Professor Ferber was appointed on February 2, 2012. Since 2017, Professor Ferber has been the Principal Investigator of cell therapy for TMU DiaCure. Professor 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 Professor Ferber's Endocrine Research Lab. Professor Ferber received Teva, Lindner, Rubin and Wolfson awards for this research. Professor 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. Professor Ferber earned her B.Sc. from Technion-Haifa, a M.Sc. in Biochemistry from Technion-Haifa and a Ph.D. in Medical Sciences from Technion-Haifa. She also holds a Post Doctorate degree in Molecular Biology from Harvard and a degree in Cell Therapy Sciences from UTSW, Dallas.

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 served at several executive positions in the field of cell therapy and medical devices with the last position was the VP of Technology & Manufacturing at Pluristem Therapeutics. He is the chair of the process and production development committee of the international Society for Cell Therapy and an expert member in the ISO TC276 Bioprocessing Committee. He has a PhD in biotechnology from the Sacler School of Medicine at Tel Aviv U and an MBA from the Haifa U School of Management.

Dr. Shimon Hassin – *Chief Technology Officer.* Dr. Hassin has over 20 years' experience in Biotechnology, with specific expertise in the development of biopharmaceuticals. Dr. Hassen was co-founder and CEO of Kadimastem, an embryonic stem cell company developing an artificial pancreas to cure Juvenile Diabetes. He worked at InSight Biopharmaceuticals an Israeli company active in Biogenerics, where he was head of process development. Dr. Hassin holds a PhD in Biotechnology from the University of Maryland Biotechnology Institute.



Dr. Denis Bedoret – *General Manager of MaSTherCell S.A.* Dr. Bedoret was appointed General Manager of MaSTherCell on July 6, Dr. Bedoret joined MaSTherCell in October 2016 as Chief Business and Administration Officer. Prior to joining MaSTherCell, from January 2014 to September 2016, he held the position of Chief Operations Officer at Quality Assistance, a leading European analytical CRO where he was also member of the board of directors. He holds a degree in Veterinary Medicine, a Ph.D. in Life Sciences from ULg and a post-doctorate degree in Immunology from Harvard Medical School.

Robert Beckman, *Director of Corporate Development*. He has served in a wide range of corporate and industry leadership positions in the healthcare sector. In pharmaceuticals and biotechnology, he led corporate business units and completed a management buy-out. Mr. Beckman served as Vice President, Marketing Services, at Revlon Health Care Group (which included USV Pharmaceutical Corp. and Armour Pharmaceutical Company) until he was appointed Vice President and General Manager of the Biochemical and Diagnostic Division of Revlon Healthcare Group. Mr. Beckman was instrumental in the formation of two of the leading biotechnology associations in the US; the Biotechnology Industry Organization (BIO) and the New York Biotechnology Association (NYBA). At BIO, Mr. Beckman served as a founding Board Member, member of the Executive Committee, and Chairman of the Emerging Company Board of Governors. He holds a B.S. Pharm Degree from Columbia University.

Patents

Orgenesis has exclusive rights to 4 US patents, one of which is a composition consisting of a vector with a promoter linked to PDX-1 which has term of until 2021. The other three have a term of until 2023 and include methods of inducing endogenous PDX-1 expression in a human differentiated primary non-pancreatic cell, inducing or enhancing a pancreatic islet cell phenotype in non-pancreatic cells, and increasing PDX-1 induction in non-pancreatic primary cells.

Orgenesis has exclusive rights to 4 foreign issued patents: 1) one in Europe that is validated in Germany, France, Italy, and the UK with a term of 2020; 2) 2 in Australia /with a term of 2020 and 2024; and 3) 1 in Canada with a term of 2020.

There are also pending applications including 5 in the US that if granted would have a term of 2034-2035. In the rest of world there are 23 pending applications that if granted would have a term of 2034 – 2025. These patents are protecting the trans-differentiation of cells (including hepatic cells) to cells having pancreatic β -cell phenotype and function, and their use in the treatment of degenerative pancreatic disorders including diabetes, pancreatic cancer, and pancreatitis.

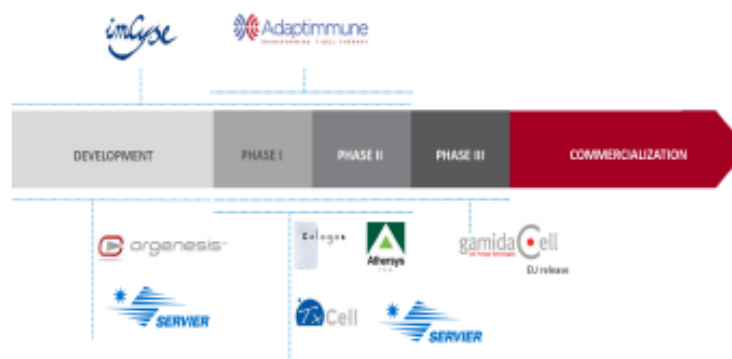
Strategic Partners and Customers

Great Point Partners (GPP): In June of 2018 ORGS signed a partnership with GPP which allows that company to invest up to \$25M into Masthercell, which would be 37.8% ownership. GPP has the right to convert its ownership into shares of ORGS at a minimum enterprise value of \$250M. ORGS received an initial payment of \$11.8M, with the balance subject to achieving certain specified EBITDA and revenue goals. Based on the current performance the next two milestones of \$7M each seem highly achievable.

Exhibit 11. Masthercell Companies

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 diagnostic MSA and full development + CTM LOI)
- ✓ Kangstem (CTM LOI + MSA)
- ✓ Reneuron (Feasibility study MSA)
- ✓ GSK (Potency assay → continuity of Adaptimmune project)







Source: Dawson James estimates.



Valuation

Our price target of \$10.00 is based on average of a 40x multiple of 2028 EPS of \$1.57 EPS discounted back at 25% and a 12.0x multiple of 2026 adjusted revenue of \$214M discounted back at 25%. We have forecasted a 5-year revenue rate of 20% annually and a 5-year EPS compounded growth of 25%. In our opinion, there is downside protection for investors since we excluded ROW sales, approval in other indications, and any pipeline value.

Exhibit 12. Sensitivity Analysis

M u l t i p l e	Discount Rate					Discounted Earnings Analysis	
	20%	25%	30%	35%			
	20	\$7.32	\$5.28	\$3.86	\$2.85	Estimated 2028 EPS	\$ 1.57
	25	\$9.15	\$6.60	\$4.82	\$3.57	Year	2028
	30	\$10.98	\$7.92	\$5.79	\$4.28	Periods (years)	8.0
	35	\$12.81	\$9.24	\$6.75	\$4.99	Price target	\$10.56
	40	\$14.64	\$10.56	\$7.72	\$5.71		
	45	\$16.47	\$11.88	\$8.68	\$6.42		
						Discounted Revenue Analysis	
	20%	25%	30%	35%	Estimated 2028 Revenues (000s)	\$ 213,927	
4.0	\$4.39	\$3.17	\$2.31	\$1.71	Year	2028	
6.0	\$6.59	\$4.75	\$3.47	\$2.57	Periods (years)	8.0	
8.0	\$8.78	\$6.34	\$4.63	\$3.42	Shares outstanding (000s):	45,316	
10.0	\$10.98	\$7.92	\$5.79	\$4.28	Price target	\$9.50	
12.0	\$13.17	\$9.50	\$6.94	\$5.13	Average Price Target Combining Both Methods		
14.0	\$15.37	\$11.09	\$8.10	\$5.99			
16.0	\$17.57	\$12.67	\$9.26	\$6.85	\$ 10.03		

Source: Dawson James Securities Research

Model Assumptions

3Q:18 EPS. CDMO has a \$1.2M profit in 2Q18, and \$2.1M in 3Q:18. Each customer represents a potential significant revenue/growth opportunity upon regulatory approval. Manufacturing costs/CDMO revenues range per customer \$10K-\$50K. In the 3Q of FY18 that ended August 31st, revenue increased 143% to \$6.2M Y/Y and 56% Q/Q. Gross profit increased 310% to \$2.9M, as compared to \$695K for the same period last year. Gross margin increased to 45.7% versus 27.1% for the third quarter of 2017. Overall the CDMO revenue has increased from a run-rate of \$3M in 2015 to \$25M in Q3:18.

Revenue. Orgenesis has several different types of arrangements with different customers. The current revenue model is based on the supply of clinical grade batches – however other models may be relevant. There is a gross profit share on cell products. And CAPEX, Consumables/disposables, and service operations are expenses. This allows for fast market penetration, short-term revenue generation, and negative impact of free cash flow (although the business is still profitable). We believe in the future that there would be a revenue share, with CAPEX as expenses, with consumables/disposables and services operations providing revenue.



The company is considering other models with less upfront investment and more revenues later. On average, the company derives revenues of \$10K-\$50K/patient.

Right now, there are 16 clean rooms in Belgium and Korea. Next year we expect 26 clean rooms to be available for manufacturing.

The company also receives grants.

Exhibit 13. Revenue Projections

Revenue	2023	2024	2025	2026	2027	2028	5yr CAGR
	\$ 103,232	\$ 119,735	\$ 144,798	\$ 169,595	\$ 191,129	\$ 213,927	~20%

Source: Dawson James Securities Research.

Gross margins continue to improve: 45% in 2Q:18, and 46.4% in 3Q:18. We have modeled 52% in outer years for the CDMO business.

EPS We estimate the first year of profitability in 2021 and a 25%-year compounded growth rate

Exhibit 14. EPS Projections

EPS	2023	2024	2025	2026	2027	2028	5yr CAGR
	0.33	\$ 0.52	\$ 0.82	\$ 1.10	\$ 1.32	\$ 1.57	~25%

Source: Dawson James Securities Research.

R&D: To date, the CDMO business is funding the CT research. We expect this to continue.

S, G&A. The company has approximately 150 people on its way to 300 which we estimate could occur within the next 12 -15 months. Many of these employees are on the Quality Control (QC) manufacturing side.

Cash: As of August 31st, 2018, quarter the company has \$16.7M in cash. The company has already achieved two \$7M payments from the Great Point Partners partnership. Also, the company receives payments from its company and hospital partnerships quarterly. Based on the current operating plan the company has enough cash to fund operations for at least 12 months.

Shares: As of October 12, 2018, there were 15.6M shares outstanding. That does not include 6,048,269 shares underlying outstanding options and warrants and 201,416 shares upon conversion of convertible notes for the six months ended May 31, 2018.

NOL: As of August 31st, 2018, the accumulated deficit was \$57.4M.



Exhibit 15. Historical and Projected Income Statement

Orgenesis

Income Statement

(in \$000 except per share values)

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	Feb Q1:18A	May Q2:18A	Aug Q3:18A	Nov Q4:18E	2018E	Feb Q1:19E	May Q2:19E	Aug Q3:19E	Nov Q4:19E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E
AIP risk adjusted sales															8,760	26,610	45,497	60,826	77,110
Licensing/Milestone Revenue	\$ 2,636	\$ 3,987	\$ 6,230	\$ 8,000	\$ 20,853	\$ 9,500	\$ 10,500	\$ 12,000	\$ 13,500	\$ 45,500	\$ 58,173	\$ 77,569	\$ 94,687	\$ 103,232	\$ 110,975	\$ 118,188	\$ 124,098	\$ 130,302	\$ 136,818
Total Revenue (000s)	\$ 2,636	\$ 3,987	\$ 6,230	\$ 8,000	\$ 20,853	\$ 9,500	\$ 10,500	\$ 12,000	\$ 13,500	\$ 45,500	\$ 58,173	\$ 77,569	\$ 94,687	\$ 103,232	\$ 110,975	\$ 118,188	\$ 124,098	\$ 130,302	\$ 136,818
COGS	1,644	2,195	3,381	4,160	\$ 11,380	4,940	5,460	6,240	7,020	\$ 23,660	30,250	40,336	49,237	53,681	59,459	66,780	73,630	79,922	86,567
Gross Profit	992	1,792	2,849	3,840	9,473	4,560	5,040	5,760	6,480	21,840	27,923	37,233	45,450	49,552	60,276	78,019	95,965	111,206	127,360
Operating Expenses																			
R&D	766	788	1,092	1,450	\$ 4,096	\$ 1,500	\$ 1,600	\$ 1,600	\$ 1,700	\$ 6,400	\$ 6,720	\$ 7,056	\$ 7,762	\$ 8,150	\$ 8,557	\$ 8,985	\$ 9,434	\$ 9,906	\$ 10,401
Amortization of Intangible Assets	436	445	505	510	\$ 1,896	\$ 520	\$ 525	\$ 530	\$ 540	\$ 2,115	\$ 2,327	\$ 2,559	\$ 2,815	\$ 3,097	\$ 3,406	\$ 3,747	\$ 4,122	\$ 4,534	\$ 4,987
S,G & A	3,344	3,323	4,008	4,500	\$ 15,175	\$ 4,750	\$ 4,900	\$ 5,250	\$ 5,500	\$ 20,400	\$ 22,440	\$ 23,562	\$ 24,740	\$ 25,977	\$ 27,276	\$ 28,640	\$ 30,072	\$ 31,575	\$ 33,154
Other Income	316	-	(2,921)	-	\$ (2,605)	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Total Operating Expenses	4,556	2,684	6,460	18,562	6,770	7,025	7,380	7,740	28,915	31,487	33,177	35,317	37,223	39,239	41,372	43,628	46,015	48,542	
Operating Income (loss)	(3,238)	(2,764)	645	(2,620)	\$ (7,977)	(2,210)	(1,985)	(1,620)	(1,260)	(7,075)	(3,563)	4,056	10,133	12,328	21,036	36,647	52,337	65,191	78,818
Financial (Income) Expenses, net	2,681	(587)	1,070	(500)	\$ 2,664	1,000	(500)	1,000	(500)	\$ 1,000	\$ 2,000	\$ (2,000)	\$ (2,000)	\$ (3,500)	\$ (5,000)	\$ (6,500)	\$ (8,000)	\$ (10,000)	\$ (15,000)
Share in net losses of ass. Company	46	576	202	250	\$ 1,074	300	500	200	250	\$ 1,250	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)	\$ (1,000)
Pre-tax Income	(603)	(2,753)	1,917	(2,870)	\$ (4,309)	(3,210)	(1,485)	(2,620)	(760)	(8,075)	(5,563)	6,056	12,133	15,828	26,036	43,147	60,337	75,191	93,818
Taxes	(396)	(277)	2,353	(500)	\$ 1,180	\$ (450)	\$ 750	\$ (500)	\$ 1,000	\$ 800	(1,335)	1,453	2,912	3,799	6,249	10,355	14,481	18,046	22,516
Tax rate	66%	10%	123%	17%	54%	14%	nm	19%	nm	17%	24%	24%	24%	24%	24%	24%	24%	24%	24%
NET Loss	(999)	(2,476)	4,270	(3,370)	\$ (2,575)	(2,760)	(2,235)	(2,120)	(1,760)	\$ (8,875)	(6,898)	7,509	15,045	19,627	32,285	53,502	74,818	93,237	116,334
Net Income Attr. To Redeemable no	134	138	800	500	\$ 1,572	200	500	500	250	\$ 1,450	\$ 1,250	\$ 1,100	\$ 1,000	\$ 1,000	\$ 1,200	\$ 1,350	\$ 1,450	\$ 1,550	\$ 1,600
Net Income	(865)	(2,614)	(5,070)	(3,870)	\$ (12,419)	\$ (2,760)	\$ (2,235)	\$ (2,120)	\$ (1,760)	\$ (8,875)	\$ (4,228)	\$ 4,602	\$ 9,221	\$ 12,029	\$ 19,788	\$ 32,792	\$ 45,856	\$ 57,145	\$ 71,302
Foreign currency translation adjne	\$ 14	\$ (10)	\$ -	\$ (15)	\$ (11)	\$ 10	\$ (18)	\$ 20	\$ (25)	\$ (13)	\$ (25)	\$ (25)	\$ (25)	\$ (25)	\$ (25)	\$ (25)	\$ (25)	\$ (25)	\$ (25)
Comprehensive loss	\$ (879)	\$ (2,604)	\$ (5,070)	\$ (3,855)	\$ (12,408)	\$ (2,770)	\$ (2,217)	\$ (2,140)	\$ (1,735)	\$ (8,862)	\$ (4,203)	\$ 4,627	\$ 9,246	\$ 12,054	\$ 19,813	\$ 32,817	\$ 45,881	\$ 57,170	\$ 71,327
GAAP EPS - basic and diluted	\$ (0.08)	\$ (0.20)	\$ (0.35)	\$ (0.25)	\$ (0.88)	\$ (0.14)	\$ (0.11)	\$ (0.11)	\$ (0.09)	\$ (0.45)	\$ (0.17)	\$ 0.14	\$ 0.27	\$ 0.33	\$ 0.52	\$ 0.82	\$ 1.10	\$ 1.32	\$ 1.57
Basic Shares	10,776	13,140	14,335	15,571	13,456	19,602	19,641	19,681	19,720	19,661	24,114	28,597	29,169	31,752	32,387	33,035	33,695	34,369	35,057
Diluted Shares			14,335	15,571	14,953	23,681	23,729	23,776	23,824	23,752	28,300	33,324	33,991	36,330	38,057	39,818	41,615	43,447	45,316

Source: Company reports, Dawson James Securities Research.



Exhibit 16. Revenue Projections

Orgenesis
Revenue Model
(in \$000s)

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Total Pancreatectomy

US	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Diagnosed Pancreatic cancer	56,549	57,680	58,833	60,010	61,210	62,434	63,683	64,957	66,256	67,581
available for surgery 30%	16,965	17,304	17,650	18,003	18,363	18,730	19,105	19,487	19,877	20,274
Pts appropriate for txt 100%	16,965	17,304	17,650	18,003	18,363	18,730	19,105	19,487	19,877	20,219
Penetration				1%	3%	5%	7%	9%	11%	13%
Patients treated			-	180	551	937	1,337	1,754	2,186	2,109
Cost \$40,000/cycle	\$ 40,000	\$ 40,800	\$ 41,616	\$ 42,448	\$ 43,297	\$ 44,163	\$ 45,046	\$ 45,947	\$ 46,866	\$ 47,804
Sales	\$ -	\$ -	\$ -	\$ 7,641,976	\$ 23,852,136	\$ 41,359,603	\$ 60,242,743	\$ 80,584,136	\$ 102,470,787	\$ 100,795,483
US sales (Risk Adjusted - 50%)	\$ -	\$ -	\$ -	\$ 3,820,988	\$ 11,926,068	\$ 20,679,801	\$ 30,121,372	\$ 40,292,068	\$ 51,235,394	\$ 50,397,742

Total Pancreatectomy

EU (Big Five)

Year	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Diagnosed Pancreatic cancer	55,418	56,526	57,657	58,810	59,986	61,186	62,409	63,658	64,931	66,229
available for surgery 30%	16,625	16,958	17,297	17,643	17,996	18,356	18,723	19,097	19,479	19,869
Pts appropriate for txt	16,625	8,479	8,649	8,821	8,998	9,178	9,361	9,549	9,740	9,934
Penetration				1%	3%	5%	7%	9%	11%	13%
Patients treated				88	270	459	655	859	1,071	1,291
Cost \$32,000/cycle	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200	\$ 3,200
Sales	\$ -	\$ -	\$ -	\$ 282,287	\$ 863,799	\$ 1,468,458	\$ 2,096,958	\$ 2,750,011	\$ 3,428,347	\$ 4,132,716
EU sales (Risk Adjusted - 50%)	\$ -	\$ -	\$ -	\$ 141,144	\$ 431,899	\$ 734,229	\$ 1,048,479	\$ 1,375,005	\$ 1,714,173	\$ 2,066,358
Worldwide Sales	\$ -	\$ -	\$ -	\$ 7,924,263	\$ 24,715,934	\$ 42,828,061	\$ 62,339,702	\$ 83,334,147	\$ 105,899,134	\$ 104,928,199
Risk Adjusted Worldwide Sales - 50%	\$ -	\$ -	\$ -	\$ 3,962,132	\$ 12,357,967	\$ 21,414,031	\$ 31,169,851	\$ 41,667,073	\$ 52,949,567	\$ 52,464,100

Chronic pancreatitis

US	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Chronic pancreatitis hospitalizations	82,500	84,150	85,833	87,550	89,301	91,087	92,908	94,767	96,662	98,595
available for surgery 25%	20,625	21,038	21,458	21,887	22,325	22,772	23,227	23,692	24,165	24,649
Pts appropriate for txt 100%	20,625	21,038	21,458	21,887	22,325	22,772	23,227	23,692	24,165	24,649
Penetration				1%	3%	5%	6%	7%	8%	9%
Patients treated			-	219	670	1,139	1,394	1,658	1,933	2,218
Cost \$40,000/cycle	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000	\$ 40,000
Sales			\$ -	\$ 8,754,966	\$ 26,790,196	\$ 45,543,333	\$ 55,745,040	\$ 66,336,597	\$ 77,329,519	\$ 88,735,623
US sales (Risk Adjusted - 50%)			\$ -	\$ 4,377,483	\$ 13,395,098	\$ 22,771,667	\$ 27,872,520	\$ 33,168,299	\$ 38,664,760	\$ 44,367,812

EU -	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Chronic pancreatitis hospitalizations	79,200	80,784	82,400	84,048	85,729	87,443	89,192	90,976	92,795	94,651
available for surgery 25%	19,800	20,196	20,600	21,012	21,432	21,861	22,298	22,744	23,199	23,663
Pts appropriate for txt 100%	4,950	5,049	5,150	5,253	5,358	5,465	5,575	5,686	5,800	5,916
Penetration				1%	1%	2%	2%	3%	4%	5%
Patients treated				26	54	82	111	142	232	296
Cost \$40,000/cycle				\$ 32,000	\$ 32,000	\$ 32,000	\$ 32,000	\$ 32,000	\$ 32,000	\$ 32,000
Sales			\$ -	\$ 840,477	\$ 1,714,573	\$ 2,623,296	\$ 3,567,683	\$ 4,548,795	\$ 7,423,634	\$ 9,465,133
EU sales (Risk Adjusted - 50%)			\$ -	\$ 420,238	\$ 857,286	\$ 1,311,648	\$ 1,783,841	\$ 2,274,398	\$ 3,711,817	\$ 4,732,567
WorldWide sales Sales			\$ -	\$ 9,595,443	\$ 28,504,769	\$ 48,166,629	\$ 59,312,722	\$ 70,885,393	\$ 84,753,153	\$ 98,200,756
Risk Adjusted Worldwide sales - 50%			\$ -	\$ 4,797,721	\$ 14,252,384	\$ 24,083,315	\$ 29,656,361	\$ 35,442,696	\$ 42,376,576	\$ 49,100,378

	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
Total Worldwide sales	\$ -	\$ -	\$ -	\$ 17,519,706	\$ 53,220,703	\$ 90,994,690	\$ 121,652,424	\$ 154,219,539	\$ 190,652,287	\$ 203,128,956
Total WW Risk Adj sales	\$ -	\$ -	\$ -	\$ 8,759,853	\$ 26,610,351	\$ 45,497,345	\$ 60,826,212	\$ 77,109,770	\$ 95,326,144	\$ 101,564,478

Source: Dawson James Securities Research.



Exhibit 17. Historical Balance Sheet

Orgenesis Inc.

Balance Sheet

(in \$000s except per share values)

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	Nov Q4:16	Feb Q1:17	May Q2:17	Aug Q3:17	Nov Q4:17	Feb Q1:18	May Q2:18	Aug Q3:18
Current Assets								
Cash and cash equivalents	891	3,872	658	762	3,519	4,225	4,502	16,741
Restricted cash	5	5	6	6	-	-	383	396
Accounts receivable, net	1,229	1,533	2,961	2,106	1,336	1,202	1,298	4,154
Prepaid expenses and other receivables	779	1,317	1,453	1,668	841	909	3,408	1,437
Receivables from related party	-	-	-	-	691	615	1,377	-
Call option derivative	-	-	-	-	-	-	792	-
Grants receivable	906	13	134	173	183	737	749	267
Inventory	400	614	904	965	725	881	1,229	1,659
Total current assets	4,210	7,354	6,116	5,680	7,295	8,569	13,738	24,654
Bank Deposits								91
Call option derivative	-	-	-	-	339	339	-	
Investments in associates, net	-	79	252	475	1,321	1,712	1,136	
Property and equipment, net	4,573	4,584	4,807	5,025	5,104	5,617	7,517	11,056
Intangible assets, net	15,050	14,626	14,969	15,480	15,051	15,076	14,011	17,576
Goodwill	9,584	9,557	10,048	10,683	10,684	11,013	10,549	15,632
Other non-current assets	70	72	75	79	78	85	82	287
Total non-current assets	29,277	28,918	30,151	31,742	32,577	33,842	33,295	44,642
Total Assets	33,487	36,272	36,267	37,422	39,872	42,411	47,033	69,296
Current liabilities								
Accounts payable	4,554	4,056	3,541	3,689	3,914	3,838	2,388	2,962
Accrued expenses and other payables	1,205	2,041	1,375	1,408	1,435	1,452	1,104	811
Employees and related payables	1,680	1,589	2,219	2,343	2,961	2,343	2,303	2,312
Related parties	42	42	42	44	116	-	126	177
Advanced payments on account of grant	243	2,205	2,101	1,978	1,719	1,703	1,415	2,619
ST loans & current maturities of LT loans	1,111	734	647	376	1,111	391	376	661
Other	21	110	-	-	-	-	107	190
Deferred income	1,273	2,721	4,264	4,944	3,611	4,870	4,596	4,863
Current maturities of convertible loans	2,541	4,625	1,958	2,789	2,780	1,567	557	358
Convertible bonds	1,818	-	-	-	-	-	-	-
Price protection derivative	76	-	-	-	-	-	-	-
Investments in associate, net	12	-	-	-	-	-	-	-
Total current liabilities	14,576	18,123	16,147	17,571	16,914	16,164	12,972	14,953
Long-Term Liabilities								
Loans payable	3,291	3,314	3,284	3,397	2,118	2,085	1,902	1,800
Convertible loans	1,059	1,679	1,772	1,444	2,415	482	-	-
Warrants	1,843	4,790	2,861	873	-	-	-	-
Retirement benefits obligation	5	5	5	5	6	6	5	430
Deferred taxes	1,862	2,373	2,027	2,608	690	312	32	2,979
Other long-term liabilities	273	273	273	273	-	-	199	524
Total long-term liabilities	8,333	12,434	10,222	8,600	5,229	2,885	2,138	5,733
Total Liabilities	22,909	30,557	26,369	26,171	22,143	19,049	15,110	20,686
Commitments								
Redeemable Non-Controlling Interest					3,606	3,884	6,122	18,646
Stockholders' equity:								
Common stock	12	12	12	12	1	1	1	1
Additional paid in capital	41,605	45,062	48,898	50,518	55,334	61,079	76,831	80,889
Receipts on account of shares to be allotted	-	774	596	852	1,483	5,997	238	5,490
Accumulated other comprehensive income	(1,205)	(1,300)	(216)	1,214	1,425	2,132	1,076	660
Accumulated deficit	(29,834)	(38,833)	(39,392)	(41,345)	(44,120)	(49,731)	(52,345)	(57,415)
non-controlling interests								339
Total stockholders' equity (deficit)	10,578	5,715	9,898	11,251	14,123	19,478	25,801	29,964
Total liabilities and stockholders' equity	33,487	36,272	36,267	37,422	39,872	42,411	47,033	69,296

Source: Company Reports.



Risk Factors: In addition to normal economic and market risk factors that impact most equities and the common risks shared by ORGS and other companies in the industry, we believe an investment in ORGS involves the following risks:

Reliance on key management – ORGS relies on several key members of its management team who either founded the company or have been in key executive positions for an extended period. Should one or more of these key executives leave the Company, ORGS could find it difficult to replace their long-standing knowledge of operations and industry expertise.

Reliance on Masthercell Global's success – To date, Orgenesis has only one signed major partner, GPP, for Masthercell and is somewhat dependent on that relationship working out as GPP is a 37.8% owner. In addition, Orgenesis has not signed major development partnerships and/or agreements for its pharmaceutical technologies and products but may do so in the future. Thus, in the future certain factors related to product commercialization and new product development may be determined by third parties and out of the control of company management.

Limited stock liquidity – Trading volume in ORGS stock is comparatively light and these shares have a relatively limited history of trading on major US stock exchanges compared with other healthcare stocks. As such, news regarding Orgenesis, its target market, partners and/or competitors could lead to significant volatility in the stock price.

Competitive Markets – Although we cannot find any public companies directly competitive with ORGS, there may be some private companies and there may be some larger manufacturing companies that may try to develop capability to produce cell and gene therapies. There can be no assurance that the company will be able to successfully compete and launch new products into these competitive markets in the future.

FDA and regulatory risks – ORGS and its partners are subject to regulatory review for its ongoing research and development activities as well as its proprietary GMP manufacturing worldwide. The quality assurance and manufacture of the company's cell and gene therapies are subject to ongoing oversight and regulation, and any negative correspondence from the FDA or other regulatory agencies could have an adverse effect on the ongoing operations.

The need to raise capital – Although ORGS's Masthercell division has achieved operating profitability on an annual basis these funds are supporting the company's therapeutic efforts. Therefore, we do not expect the company to be profitable for several years, and according to our forecasts profitability may not be until 2021. Although Orgenesis maintains adequate cash reserves now, there can be no assurance the company will not need to raise additional working capital in the future should operating losses continue.

Need to defend patents and other intellectual property – ORGS currently hold several US and International patents on its products and related technologies. The Company may be required to defend its patents in the US and overseas in the future, and there can be no assurance these defenses will be successful.

Reliance on partners – ORGS has many partnerships and some revenues are dependent on those products to be successful.



Companies mentioned in this report:

Adaptimmune (ADAP, not rated)

AgenTus Therapeutics (subsidiary of Agenus, Inc, AGEN, not rated)

Apceth Biopharma GmbH (private)

Biotech Innovative Manufacturing Services (formally Eufets GmbH) (private)

Cell Therapy Catapult Limited (private)

Cognate Bioservices Inc. (private)

CRISPER Therapeutics (CRSP, not rated)

Dendreon (acquired by Valent Pharmaceuticals (VRX, not rated)

Fraunhofer Gesellschaft, Cellforcure SASU (private)

Gamida Cell (private)

Iovance Biotherapeutics (IOVA, not rated)

KangStem Biotechnology (KOSDAQ: 217730, not rated)

Lonza Group Ltd (LZAGY, not rated) Pharmacell BV (acquired by Lonza)

Molmed S.p.A. (MLMD.MI/ MLM IM, not rated)

ProQR (PRQR, not rated)

Progenitor Cell Therapy (PCT) LLC, (acquired by Hitachi)

ReNeuron (AIM: RENE, not rated)

Servier (Private)

ThermoFisher Scientific/ Patheon (TMO, not rated)

WuxiAppTec (WuXi PharmaTech) (2269:HK)

Zelluna Therapeutics (private)



Important Disclosures:



Source: FactSet

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- 1) **Buy:** the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutral:** the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sell:** the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

The following chart reflects the range of current research report ratings for all companies followed by the analysts of the Firm. The chart also reflects the research report ratings relating to those companies for which the Firm has performed investment banking services in the last twelve months.

	Company Coverage		Investment Banking	
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals
Market Outperform (Buy)	41	89%	10	24%
Market Perform (Neutral)	5	11%	0	0%
Market Underperform (Sell)	0	0%	0	0%
Total	46	100%	10	22%

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