

# Orgenesis

03:15 12 Mar 2019

## Orgenesis leads the charge at an exciting time for cell therapy

- The Germantown, Maryland-based biopharmaceutical company has expertise in developing advanced cell therapies and manufacturing.
- Its MaSTherCell Global subsidiary is a global contract development and manufacturing organization, or CDMO.
- Masthercell Global generated \$22.6 million in sales and an operating profit of \$4 million on a standalone basis in 2018.
- Oslo-based Zelluna Immunotherapy has selected MaSTherCell as its manufacturing partner for its T-cell receptor immunotherapies targeting cancer antigens
- Orgenesis is a pioneer in transdifferentiation, which involves direct reprogramming of an adult tissue or cell into another type of specialized cell

### Company overview

Orgenesis Inc (NASDAQ:ORGS) is a vertically integrated biopharmaceutical company with expertise in developing advanced cell therapies and manufacturing.

On the manufacturing side, the company's subsidiary MaSTherCell Global is a global contract development and manufacturing organization, or CDMO. MaSTherCell helps companies shorten lead time and lower costs in getting cell therapies and products to the market.

On the technology side, the company's subsidiary Orgenesis Ltd, is a pioneer in transdifferentiation, which simply means cell reprogramming. It has utilized its proprietary technology to successfully reprogram human liver cells into glucose-responsive, fully functional, insulin-producing cells.

### Spurring the arrival of new therapies

MaSTherCell Global has facilities in Europe, Israel through Atvio-Biotech and through subsidiaries in Asia and the US.

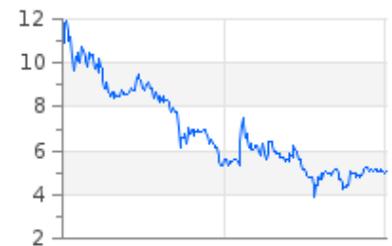
It helps customers — pharma, cell, gene therapy companies, as well as research institutions and hospitals — with tech selection, assay development, cell therapy manufacturing and business modeling. This helps speed up the arrival of therapies to market.

"Orgenesis brings the two worlds together — the engineering world and the biological world," Vered Caplan, the CEO of the company, told Proactive Investors. "We really focus on industrializing drugs," added Caplan, an industry veteran with bio-medical engineering and business development degrees from Tel-Aviv University, in Israel.

**Price:** US\$4.95

**Market Cap:** US\$77.32M

### 1 Year Share Price Graph



March 2018 September 2018 March 2019

### Share Information

**Code:** ORGS

**Listing:** NASDAQ

**52 week High Low**  
\$13.20 \$3.87

**Sector:** Pharma & Biotech

**Website:** www.orgenesis.com

### Company Synopsis:

*Orgenesis is a development stage company with a novel therapeutic approach in the treatment of diabetes by correcting malfunctioning organs with new functional tissues created from the patient's own existing organs. Orgenesis employs a molecular and cellular approach directed at converting liver cells into functional insulin-producing cells as a treatment for diabetes.*

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Orgenesis has a strategic partnership with Great Point Partners LLC, a healthcare investment firm in Greenwich, Connecticut which will give it \$25 million to develop global services.

MaSTherCell has received the first milestone payment of \$6.6 million from Great Point Partners and is expanding into the US by building a new 30,000 square feet manufacturing facility in Houston.

#### Expansion mode

MaSTherCell unveiled a new production wing at its Belgium site which gives it five additional clean rooms. The new wing includes two development labs, a quality control lab and warehouse capabilities.

"It was important for us to expand our current Belgium plant because the cell therapy industry, and specifically our partners, need to have access to reliable facilities for their commercial projects," said Caplan. "Our objective is to help them access the market faster with tailor-made capabilities."

Oslo-based Zelluna Immunotherapy has selected MaSTherCell as its manufacturing partner for its T-cell receptor immunotherapies targeting cancer antigens.

#### Novel technology platform

Orgenesis is also a pioneer in transdifferentiation, which involves direct reprogramming of an adult tissue or cell into another type of specialized cell with its distinct function. Transdifferentiation potentially provides the use of a patient's own adult tissues to restore any damaged organs or tissue. This ability to convert one cell type to another holds great promise in the stem cell field.

Orgenesis founder and chief scientific officer Professor Sarah Ferber is the inventor of the company's groundbreaking transdifferentiation platform technology.

Ferber, who completed a post-doctoral fellowship from Harvard Medical School, made a discovery suggesting adults carry their own stem cells, obviating the need for embryonic stem cells for generating an organ in need.

The first indication Orgenesis is pursuing is for the treatment of severe diabetes following a pancreatectomy, a surgical procedure performed to treat severe pancreatitis. Through its Israeli subsidiary, Orgenesis Ltd, the company is also targeting insulin-dependent diabetes.

Converting a diabetic's own tissue into insulin-producing cells has the potential to provide a cure for insulin dependence and overcoming donor shortages, costs and risks involved with transplant rejection.

"This is a cell taken from your own body, utilized and manipulated, so it can go back and do an even better job," said Caplan.

#### Big market opportunity

Orgenesis is eyeing an expanding cell therapy market pegged at \$32 billion.

At heart, cell therapy is the treatment of disease through cells which have been selected, multiplied and manipulated outside the body. The most common type of cell therapy is the replacement of mature, functioning cells through blood and platelet transfusions.

While academic and industrial research has led scientific development in the sector, industrialization and manufacturing expertise remains insufficient.

The beauty of Orgenesis is that has built a platform of know-how and expertise for a multitude of cell therapies including autoimmune, oncologic, neurologic and orthopedic diseases, among other indications.

Orgenesis is building a fundamental base platform of expertise for a multitude of cell types crucial for the regenerative medicine industry.

### Bullish investment case

The company is seeing steady growth on an expansion of services, particularly CAR T-cell therapies. This is a type of treatment that involves a patient's T-cells being changed in the lab, so they attack cancer cells.

Orgenesis reported a 139% expansion in profit to \$7.8 million for fiscal year 2018, compared to \$3.3 million for the previous financial year.

"We are pleased to report strong growth, increased gross profit and solid gross margin improvement in fiscal 2018," said Caplan. "Our CDMO segment, Masthercell Global generated \$22.6 million in sales, and an operating profit of \$4 million on a standalone basis. We continue to grow Masthercell's backlog and customer base."

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