

Q2-2018 Update Report

20 August, 2018

CELLECT

On track with its strategic plans; ApoGraft POC final results estimated to be published by mid-2019; sufficient cash to support clinical and preclinical trials; target price unchanged.

Primary Exchange: NASDAQ

Ticker: APOP

Sector: Biotechnology

Industry: Stem cells

Data as at 17 August, 2018

(Source: Yahoo Finance)

Closing price: \$4.97

Market cap: \$32.3M

of shares: 6.35M

Stock performance (12 mos.): -30%

Daily-trading-vol. (12 mos.): \$54,378

Stock target price: \$16.90

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Company Overview

Collect Biotechnology Ltd. (hereinafter: "Collect" or "the company") is developing a technological platform, the "ApoGraft", which functionally selects stem cells from a mixed population of cells based on their sensitivity to apoptosis. The first product under development is the ApoTainer™ selection kit. The company is currently conducting a proof-of-concept phase I/II trial with blood cancer patients in Israel. Based on trial results and safety issues, the company plans to integrate its technology into a range of procedures that utilize stem cells, as well as into the manufacturing process of adult stem cell based products.

Highlights & Analysis

Collect released its Q2-2018 report on 9 August, 2018 detailing the following:

Collect is on track with its strategic plans; minor setback in patient recruitment may delay ApoGraft POC final results till mid-2019.

- Collect announced on 9 April, 2018 that it has successfully completed the proof of concept testing of its first in type new product prototype, ApoTainer™ using its FasL-coated magnetic beads for maximizing efficacy and scalability of stem cell based products' manufacturing.
- Collect continued to enroll and treat patients in its Phase I/II clinical trial of ApoGraft™. The aim being to evaluate the technology's safety, tolerability and efficacy in functionally selecting donor derived mobilized peripheral blood cells and subsequent transplantation into patients with hematological malignancies in allogeneic hematopoietic stem cell transplantation.
- The company reported on January 2018, a 100% acceptance and zero related adverse events for the first group of three patients after a one month follow-up. Accordingly, Collect recently decided to explore the development and establishment of biobanking business opportunities based on their ApoGraft™ platform technology that may have the potential to add value to this domain.

Collect has Initiated a second program focusing on the selection of mesenchymal stem cells (MSCs) from fat cells, which poses great potential.

- Collect has initiated a second program focusing on a selection of mesenchymal stem cells (MSCs) from fat cells also called adipose stem cells (ASCs). Those cells have the potential to differentiate and regenerate into cells of mesenchymal lineage such as adipocytes (fat cells), osteoblasts (bone cells), chondrocytes (cartilage cells and other cells) and myocytes (muscle cells).

Sufficient cash to support current clinical early phase and other pre-clinical pipeline development until Q2-2019.

- Cash and cash equivalents, marketable securities and short-term deposits totaled \$8.2 million as of June 30, 2018, sufficient until Q2-2019.

We maintain our estimation of the company's equity value at \$101.4M; corresponding to a target price ranging between \$15.40 and \$18.70; a mean of \$16.90.

- In our view, the company is on track to meet its strategic goals. Should the company see positive results in its ongoing trial (ApoGraft POC final results estimated for early 2019); the financial potential of their stock is projected to increase .

Company Activity and Strategy

The company was founded in 2011, with its first indication platform, Apograft™, optimizing the selection of hematopoietic stem cells by selectively neutralizing harmful immune cells that may cause severe side effects such as GvHD (graft versus host disease) once transplanted into a patient. The technology is based on an apoptosis (programmed cell death) signal that selectively destroys some of the mature cells responsible mainly for the GvHD while maintaining the viability and functionality of the stem cell entities in the graft. The Apograft™ is currently undergoing a phase I/II open-label clinical trial in Israel involving matched related donor hematopoietic stem cell transplantations for blood cancers patients (leukemia, lymphoma and high-risk MDS patients).

The company develops a platform technology which enables enrichment of stem cells component in any starting mixed populations of cells. A simple, robust, reproducible, short and easy to use technology provides stem cells with an enriched batch of cells that can be used for any procedure requiring mature stem cells. The technology may be used in all regenerative medicine markets that use adult stem cells upon showing safety and efficiency of selection. It can be applied both as an off-the-shelf product for medical purposes and for laboratory research.

Cellect's first planned commercial product candidate is for bone marrow transplantations within the cancer therapy market. Once proof-of-concept results are obtained and safety issues are resolved, the company plans to integrate its technology in many production procedures of stem cell-based products by partnering with cell therapy companies. Additional indications such as type 1 diabetes and solid organ transplantation have also been tested and may be expanded, as well as other sources of stem cells (fat, cord blood).

In addition to the selection of hematopoietic stem cells, Cellect has initiated a second program focusing on the selection of mesenchymal stem cells (MSCs) from fat cells. In recent years, there has been increased interest in mesenchymal stem cells and their potential utility in tissue engineering and repair. Expansion of cells in culture is necessary prior to transplantation or re-introduction into the patient. Depending on the source and method of isolation, this procedure can be significantly time-consuming and expensive. Cellect's ApoGraft™ Technology, which pending approval, will be offered as an easy to use, off the shelf and scalable device, aims to mass produce those cells with increased speed, effectiveness, and cost efficiency. A rapidly increasing number of clinical trials using MSCs for multiple indications such as bone and cartilage, cardiovascular and autoimmune diseases as well as cancer, will increase demand. The company may provide a safe and cost-effective production platform to meet such market needs.

Cellect develops a unique enabling technology that provides stem cells as a raw material, and therefore holds great promise to engage in all regenerative medicine markets that use stem cells for numerous indications, a \$7.5 billion market with a rapid growth rate of 20.1% as of 2018. By enabling the use of HSCs not exclusively for malignant indications but as well for severe autoimmune deficiencies and metabolic disorders in an rapidly growing market, the potential that the company holds is high. But before using the ApoGraft™ technology broadly, the safety, efficacy and low cytotoxicity have to be proven in a first indication.

Currently, in line with its developmental stage, the company has positive data from a non-interventional study performed on samples from healthy donors. In addition, successful completion of the ongoing phase I/II proof-of-concept clinical study may provide Cellect multiple opportunities for business IP licensing deals before having a marketing approval for its products. The company has a wide IP protection to support the entire technology platform and a vast number of applications in markets worldwide.

As a relatively new form of therapeutic and mostly still in early development stages, cell therapy has yet to prove its clinical advantages and needs to reduce costs over other forms of therapeutics before widely adopted; therefore this engagement may pose a considerable risk to the company.

Q2-2018 Update

Financial Results

Research and development (R&D) expenses for the second quarter of 2018 were \$0.68 million, compared to \$0.78 million in the first quarter of 2018 and \$0.66 million in the second quarter of 2017. The decrease in the second quarter of 2018 compared to the first quarter of 2018 was primarily due to a decrease in share-based compensation

General and administrative (G&A) expenses for the second quarter of 2018 were \$0.99 million, compared to \$0.95 million in the first quarter of 2018 and \$0.96 million in the second quarter of 2017. The slight increase for the second quarter of 2018 compared to the first quarter of 2018 was primarily due to an increase in business development expenses

Financial income for the second quarter of 2018 was \$0.03 million, compared to financial income of \$0.75 million in the first quarter of 2018. The decrease was primarily due to changes related to the fair value of tradable and non-tradable warrants issued in prior rounds of capital raising

Net loss for the second quarter of 2018 was \$1.6 million (LPS of \$0.01 or \$0.25 per ADS) compared to \$0.98 million (\$0.01 or \$0.15 per ADS) for the first quarter of 2018, and \$1.3 million (\$0.01 or \$0.23 per ADS) for the second quarter of 2017

Cash and cash equivalents, marketable securities and short-term deposits totaled \$8.2 million as of June 30, 2018, compared to \$9.5 million on March 31, 2018, and \$7.6 million on December 31, 2017. The change in the cash and cash equivalents was primarily due to net proceeds of \$3.5 million from a registered direct offering completed in January 2018, offset by cash used in operations during the period

Shareholders' equity totaled \$6.1 million as of June 30, 2018, compared to \$7.4 million on March 31, 2018, and \$5.2 million at December 31, 2017

Operational and Clinical Development Highlights

Successfully completed proof of concept testing of the ApoTainer™ using Collect's FasL-coated magnetic beads for maximizing efficacy and scalability of stem cell-based product manufacturing

Opened a U.S. center of operations led by Andrew Sabatier, formerly the US Sales and Market Development Leader for GE Cell Therapy. Sabatier is heading up commercialization of Collect ApoGraft™ technology, as well as new business development.

Signed a collaboration and material transfer agreement with the denovoMATRIX group of the Technische Universität Dresden (TU Dresden), a leading center for stem cell research in Germany

Launched a collaboration with Cell2in to improve stem cell selection and expansion. Collect announced on 13 August that it signed a collaboration agreement with Cell2in, a South Korean company focused on improving the quality of cells. According to the agreement, the companies will conduct scientific evaluations combining Collect's technology platform ApoGraft™ with Cell2in's proprietary identification technology FreSHtracer™ which monitors stem cell quality by utilizing a fluorescent dye to characterize their oxidative stress state.

Granted key european patent for its stem cell selection technology that covers ApoGraft's uses, methods and devices in stem cell selection for conditions including GvHD. We expected that will give the company protection against devices that make use of apoptosis for cell selection.

Entered into a strategic manufacturing and supply agreement with Swiss Biotech Center (SBC) to secure production of FasL protein - Cellect's main active ingredient in ApoGraft™ and the ApoTainer™ for planned clinical trials in the U.S.

Analysis

Cellect has sufficient cash to support clinical development scheduled till Q2-2019. In our view, the company is on track to meet its strategic goals. Should the company see positive results in its ongoing trial (ApoGraft POC final results estimated for early 2019); the financial potential of their stock is projected to increase. We maintain our estimation of the company's equity value at \$101.4M; corresponding to a target price ranging between \$15.40 and \$18.70; a mean of \$16.90.¹

¹ For a full breakdown of our valuation methodology see our [Initiation of Coverage, dated 27 April 2017](#).

Appendix I – Financial Reports

Balance Sheet	(\$000s)	(\$000s)	(\$000s)
<u>Current Assets:</u>	<u>31.12.2016</u>	<u>31.12.2017</u>	<u>30.6.2018</u>
Cash and cash equivalents	6,279	3,961	5,706
Short term deposits	19,660	-	1,000
Marketable securities	4,997	4,038	1,507
Accounts receivable	1,461	236	254
Total – Current Assets	32,397	8,235	8,467
<u>Non-Current Assets:</u>			
Restricted cash	140	88	91
Other long term assets	-	50	42
PPE, net	1,373	388	376
Total – Assets	33,910	8,761	8,976
<u>Current Liabilities:</u>			
Trade payables	1,401	491	308
Other accounts payable	2,084	691	513
Total Current Liabilities	3,485	1,182	821
<u>Non-Current Liabilities:</u>			
Warrants exercisable into shares	1,938	2,141	2,095
Total Non-Current Liabilities	5,423	3,323	2,095
Total Liabilities	8,908	4,505	2,916
Total Equity	25,002	933	6,060
<u>Total Liabilities + Equity</u>	33,910	8,761	8,976

Statement of Profit and Loss	(\$000s)	(\$000s)	(\$000s)	(\$000s)	(\$000s)	(\$000s)
<u>Reporting Period:</u>	<u>2016</u>	<u>2017</u>	<u>31.3.2017</u>	<u>31.3.2018</u>	<u>30.6.2017</u>	<u>30.6.2017</u>
Research and development expenses	2,147	3,318	784	813	1,451	1,465
General and administrative expenses	2,072	3,729	708	982	1,680	1,938
Other Income	(73)	0	0	0	0	0
Total Operating expenses	4,146	7,047	1,492	1,795	3,131	3,403
Operating Loss	4,073	7,047	1,492	1,795	3,131	3,403
Financial expenses (income) due to warrants	172	1,123	1,881	(633)	1,476	(443)
Other financial expenses (income), net	9	29	85	(145)	130	(340)
Total loss	4,254	8,141	3,459	1,017	4,737	2,620

Appendix II - Company's Products

Cellect develops safe and cost-effective products for different stem cell treatments. Cellect technology enables the standardized selection process for stem cells resulting in the reproducible mass production of raw material from various sources and for any indication.

Cellect develops a line of products comprised of various containers such as infusion bags, flasks and test tubes designed to address different markets such as medical, research and biopharma companies. Its applications involve stem cell isolation following collection (autologous or allogeneic) and/or co-culture and expansion. It is a simple, low cost and fast procedure that does not require a special laboratory or equipment.

Selected products and their stages of development:

- ApoGraft™ – the proprietary stem cell selection process is currently being tested in an Open -Label Phase I/II clinical study in which 12 blood cancers patients will be given ApoGraft™ treated cells and their response will be compared to historical data.
- ApoTainer™ – an off the shelf device based on the ApoGraft™ technology, for which POC was shown. The first prototype is planned for the end of 2018 and product launch estimated for 2023.

Both the product and the technology are in the proof-of-concept stages and thus, investment at this time would be high risk. Clinical Trial Phase I/II results will provide Cellect clinical proof of concept and facilitate finding licensing partners.

Cellect's intellectual property is validated by proof-of-concept studies and includes 7 global patent applications covering: the concept of using apoptosis-inducing agents for stem cell selection; composition of the ApoTainer™ matter and method of manufacturing; methods of use; mesenchymal stem cell selection; Expiration dates range between 2027 and 2034. Four of those patents have already been granted in the US.

Since June 2015 Cellect has had a strategic joint product development agreement for its medical kit with **Entegris**, a US company that specializes in advanced plastic devices for high-tech industries. Entegris will be responsible for completing the design and production of the polymer product, including the development costs, while Cellect will be responsible for the biological aspect and testing (including human trials). These two companies have been also reviewed by the prestigious binational US/Israeli foundation and have received a \$1M funding.

ApoGraft™ – A Cellect Proprietary Function-Based Cell Selection Technology

What makes Cellect's process unique in principle compared to other methods available today, is that only a small subpopulation of mature cells is eliminated by the death signal. The "graft versus tumor effect", which allows some donor cells to attack any remaining cancer cells is an important role of HSCT is preserved. According to Cellect, these aspects have been tested in animal models, showing eliminated GvHD and full preservation of the anti-cancer effect, results further supported by numerous independent publications.^{1 2 3} Further preclinical data provided by Cellect are included in scientific publications under preparation.

¹ Askenasy N, et al. Biol Blood Marrow Transplant. 2013;19:185

² Mizrahi K, et al. Stem Cells and Development. March 2014, Vol. 23, No. 6: 676

³ Mizrahi K, et al. Bone Marrow Transplant. 2014 May; 49(5):640-8.

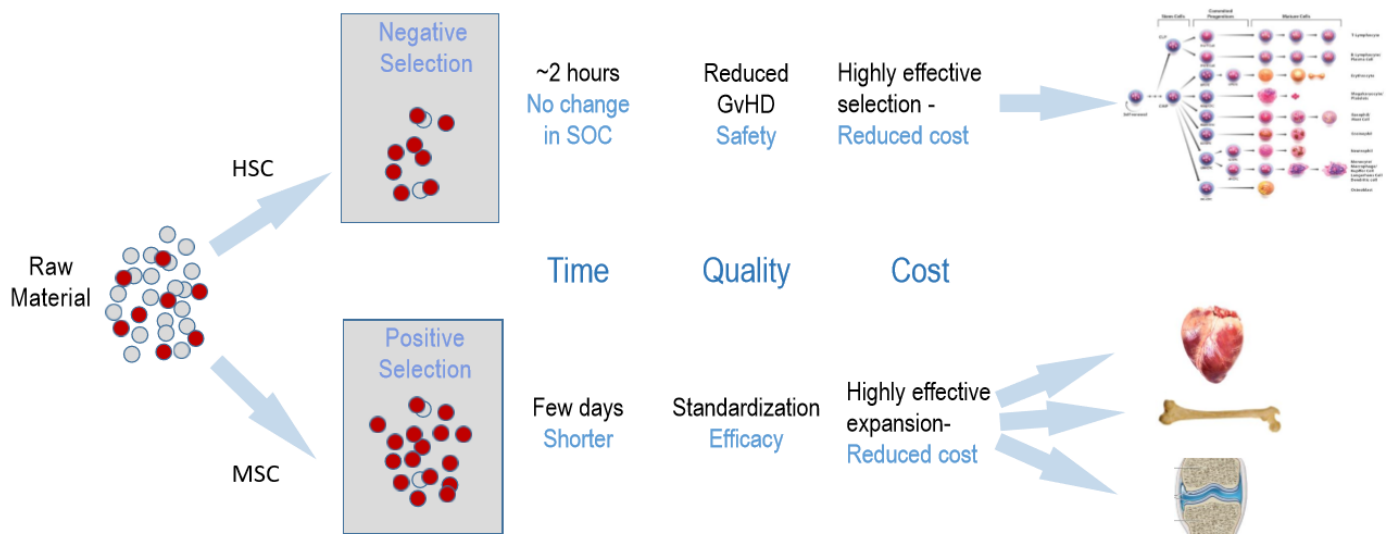


Figure 4. Collect positive and negative cell selection

Source: Collect Biotechnology Ltd.

ApoTainer™ – An Off-the Shelf Device for Hematopoietic Stem Cells for Bone Marrow Transplantations

Collect's first planned commercial product candidate is ApoTainer™, a unique plastic blood container, currently under development for the improved safety of the treatment of cancer by bone marrow transplantation by prevention of Graft versus Host disease. The design of the ApoTainer™ concept makes it scalable giving it the potential to play a crucial role in other applications, for example where large quantities of stem cells are required.

The ApoTainer™ concept is based on Collect's key ApoGraft™ technology, where subsets of adult white blood cells can be induced to undergo programmed cell death (apoptosis) under certain conditions while stem cells proved to be resistant to that biological process hence allowing functional selection of the stem cells.

The ApoTainer™ contains immobilized Fas Ligand (FasL) protein that triggers the death of some mature cells by apoptosis, allowing the remaining stem cells to flourish in their natural microenvironment (Figure 4). In the device currently under development for bone marrow transplantation, this process eliminates harmful immune cells that may trigger an immune rejection as well as GvHD responses, thus potentially reducing medical complications.

Importantly, the cells begin apoptosis and are committed to a suicide path but still stay intact during the process. Therefore, there is no need to discard or physically separate the dead cells or stem cells from the container. Instead, the container can be hooked up intravenously to the patient and the stem cells directly delivered, potentially providing an output immediately usable for any medical or research purpose of enriched hematopoietic stem cells within hours of the procedure.

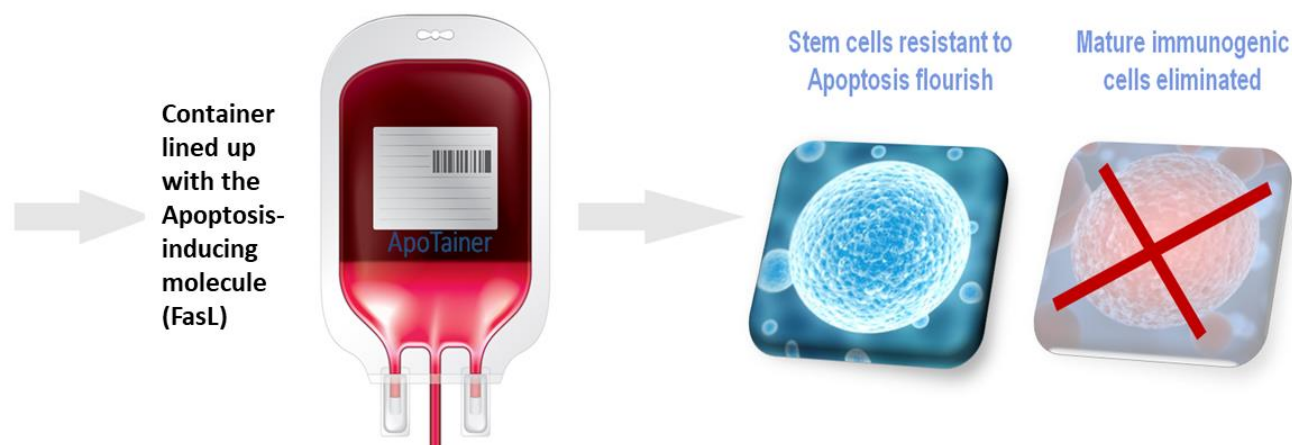


Figure5. Mechanism of Action of Collect flagship technology

Collect's overall product development strategy

Initially, the focus of the ApoGraft™ will be in hemato-oncology, which is the most popular segment for cell therapy collaborations and deals, comprising 29.2% of all the cell therapy related deals made in 2015. Close to 19% of cell therapy focuses on oncology-related products, making it the second-largest market segment. An increasing number of immunological treatments for graft versus host disease (GvHD) that include the use of Mesenchymal Stem Cells and CAR T-cells are being explored; furthermore, a combination of cell-gene and stem cell-gene with immunotherapy are used by directly transferring genes into cells for the purpose of treating hematopoietic cancers. Clinical trials using cell-gene therapy to treat terminally ill cancer patients have been successful, showing great curative potential, and pushing forward the cell therapy market. Although only 4% of the marketed products are oncology related, a large pipeline indicates that this will be a high-growth segment. Nonetheless, enabling the large-scale production of cell-gene and stem cell-gene therapies will become a vital manufacturing concern to this industry in the upcoming years. Therefore, Collect may position itself as a central player in this market segment, supporting the production procedure of multiple stem-cell companies as potential clients.

Collect's ongoing study allows the enrollment of leukemia, lymphoma and high-risk Myeloma (MDS) patients. Leukemia constitutes 3.7% of all new US cancer patients with approximately 62,130 estimated new cases in 2017 according to National Cancer Institute. Acute myeloid leukemia (AML) is the second most common type of leukemia with 21,380 estimated new cases of AML in 2017 and a five-year survival rate of approximately 26%.

Appendix III - Market Overview

The Stem Cells market, which forms part of the wider cell therapy market, has a complex operating environment. It is based on several key players in the cell therapy ecosystem (Figure 2), which are all important to understand when evaluating a company like Collect. Collect is positioned within the industry as a Biotech company, providing technology for the enrichment of stem cells that may support multiple stem cell companies and research initiatives.¹⁶

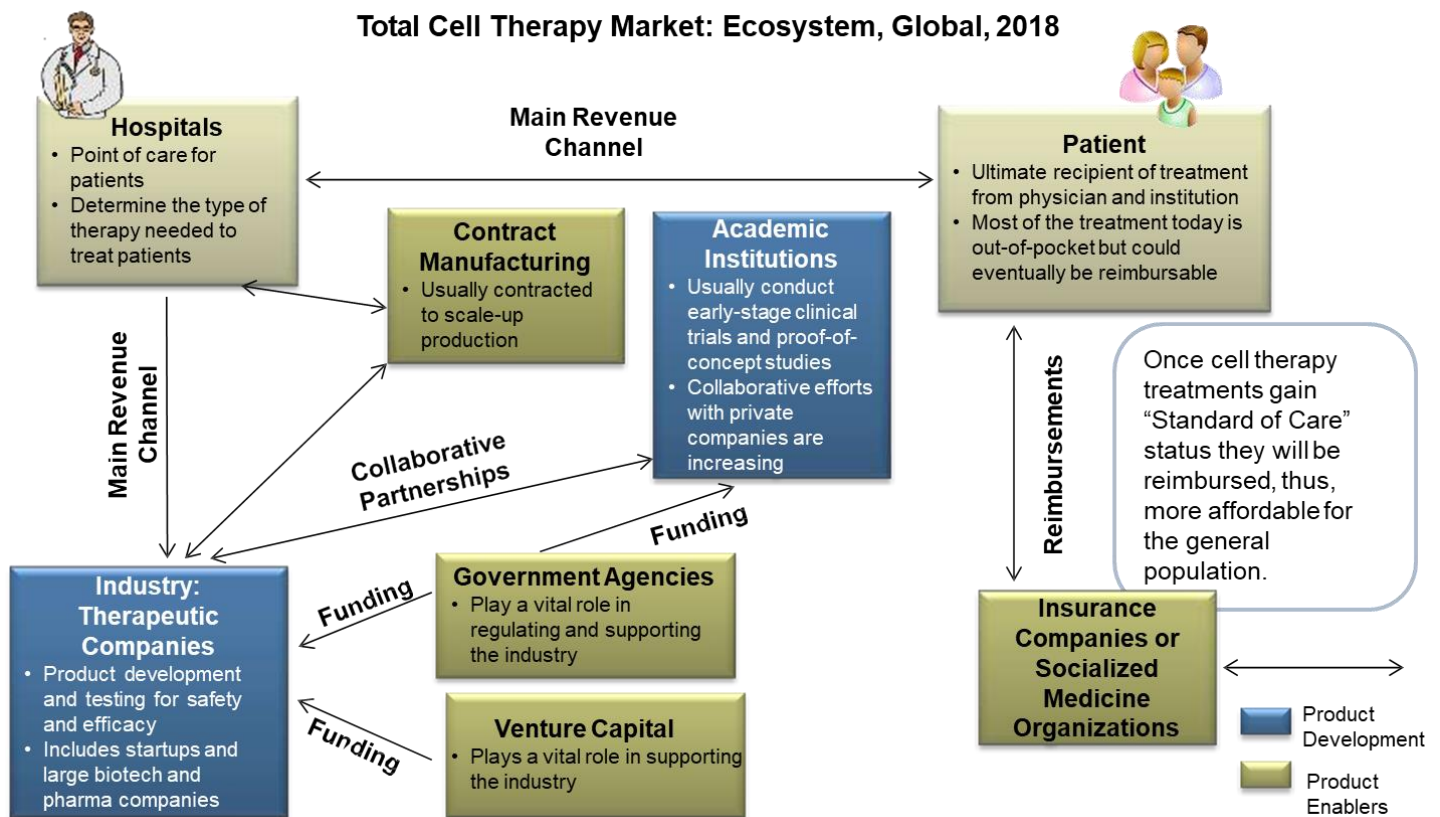


Figure 2. The Ecosystem of the Cell Therapy Market.

Source: Frost & Sullivan, *Future of Cell Therapy in the Regenerative Medicine Market*.

Stem cell therapy is the largest segment of regenerative medicine which involves the use of living cells to replace or augment damaged or diseased cells and tissue. It uses adult or embryonic stem cells to regenerate cells as a medical intervention, as well as growing large masses of cells, tissues and organs in the laboratory for transplantation into the human body. It is a new human-health paradigm designed to combat diseases like cancer that have become more common as global ageing is established. Instead of using drugs, chemicals, radiation and surgeries, this therapy replaces the damaged tissue or organ with regenerating stem cells using biological processes similar to those found in nature. By 2030, there will be globally more people over 60 than under the age of 10. Already, there are more adults over the age of 60 than children under the age of 5. Healthcare systems are burdened by costly treatments for an ageing and increasingly ailing population.

Cell therapy holds 60% of the overall regenerative (recovering) medicine market in clinical trial numbers. The cell therapy market can be viewed in four main categories: Cell-based immunotherapy; Stem cell therapy (Collect's market); Cell-gene therapy; and Stem cell-gene therapy. Closely related to this market is the supporting technologies field that includes cell acquisition, cryopreservation, cell production, expansion and sub-culture. Collect's technology relates to cell production and expansion.

An overview of the market:

Established Cell Therapy Companies	Cell therapy is a fast-growing, emerging market. Stem cell therapy, comprising the largest part of the market, has the largest number of clinical trials globally. Furthermore, combination therapies, such as stem cell-gene and cell-gene, are showing great curative potential, which has led to US Food and Drug Administration (FDA) fast-track status.
Small- to Medium-sized Companies	Significant opportunities exist for small- to medium-sized companies in this rapidly expanding market. With growing government and private funds, the global market is ripe for new companies with innovative therapies to come to the forefront.
Pharmaceutical Companies	Large pharmaceutical companies such as Pfizer, Novartis, and Juno Therapeutics are entering the market because there is strong evidence of the safety and efficacy of numerous products in the pipeline. In addition, the curative potential of some of the cell-gene therapies is driving the creation of new partnerships, mergers, and acquisitions.
Support Industry Expansion	As the commercial production of stem cell, cell, and gene therapies increases, the need for fully-enclosed systems, such as bioreactors, and disposable products for Current Good Manufacturing Practice (CGMP) production will also grow.
Manufacturing Facilities	Very few large-scale manufacturing facilities exist. The cost of goods sold is high relative to marketable product output. Vector production capabilities are currently limiting the rate of production for stem cell-gene and cell-gene products.

Figure 3. Market Overview

Source: Frost & Sullivan, *Future of Cell Therapy in the Regenerative Medicine Market*

Cell therapy is already treating millions of patients globally and will probably disrupt the pharmaceutical landscape and revolutionize the way that patients are medicated in the future. There are over 500 companies active globally, with more than 50% located in the United States. The market potential is the largest in the United States but is also growing rapidly in Japan and South Korea due to the implementation of the favorable government policies.

The United States has the largest number of industry-based clinical trials despite stringent regulations, as well as the largest number of private cell therapy companies. Europe is surprisingly lagging behind the United States in cell therapy, with the United Kingdom and Germany at the forefront in this region. Because of Japan's relaxed regulations, it is becoming hotspot for innovation, and foreign partnerships are welcome, while reimbursement standards are being re-evaluated. The Chinese government welcomes foreign investment, collaborations and partnerships, although there are some ethical as well as quality concerns that are being currently addressed by the government.

The total cell therapy market size in 2018 is estimated at nearly \$7.5 billion and is set to grow at a compound annual growth rate (CAGR) of 20.1% until 2020. Although the United States dominates the market, relaxation of government regulations opens new opportunities in Asia, especially in countries like Japan.

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