Trinity Delta

MaxCyte

Outlook

Momentum building in Cell Therapy and CARMA

5 December 2018

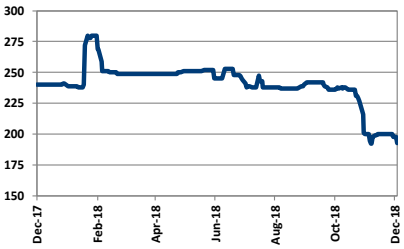
MaxCyte's hybrid business model continues to advance strongly on all fronts. Two new commercial licenses for cell therapies have recently been announced, in addition to dosing of the first patient with a CARMA product. Initial data from the MCY-M11 Phase I study, expected in early 2019, will give the first indication of how CARMA therapies may be used to treat solid tumours. The product/service business continues to deliver sustained double-digit revenue growth, and this growth rate should accelerate as MaxCyte's broad portfolio of clinical and commercial licenses expands. The number of clinical use licenses grew from >15 to >25 over the past year, which will increase near-term revenues and raises the likelihood of additional commercial licensing agreements. We value MaxCyte at £177m, or 347p/share.

Year-end: December 31	2016	2017	2018E	2019E
Sales (US$m)	12.3	14.0	17.0	20.5
Adj. PBT (US$m)	(3.3)	(9.9)	(11.4)	(14.5)
Net Income (US$m)	(3.9)	(9.9)	(11.4)	(14.5)
EPS (USc)	(10.0)	(20.4)	(22.2)	(28.2)
Cash (US$m)	11.7	25.3	13.8	0.6
EBITDA (US$m)	(2.6)	(9.1)	(10.4)	(13.5)

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals

- **The first CARMA clinical trial is underway** The first patient has received therapy in the c 15-patient Phase I MCY-M11 (anti-mesothelin) study in ovarian cancer and peritoneal mesotheliomas. This is the first clinical trial with a CARMA product. CARMA is a novel chimeric antigen receptor (CAR) cell therapy, developed solely by MaxCyte with its core flow electroporation technology. It promises to overcome many of the limitations of the current CAR-T cell technologies, which are restricted to haematological cancers due to on target/off tumour effects.
- **Data will soon make clear CARMA's potential** The trial has already validated MaxCyte's ability to produce the cell therapy within a day (vs 1-2 weeks with current CAR-T therapies). First clinical data will start to be reported from early 2019. The primary endpoint is tolerability, but the higher dose levels should also produce some efficacy signals. In previous studies with mRNA-CAR-T therapies, there has been promising anti-tumour activity, even though the T-cells express the CAR only transiently, unlike with Novartis' Kymriah and Gilead's Yescarta.
- **Growth in core business underpins the company** Advances in cell therapies, gene-editing including CRISPR, and immuno-oncology, together with MaxCyte's leading position in high-performance flow electroporation, have sustained double-digit sales growth. In H118, sales grew by 12%; we forecast that sales growth will accelerate to c 20% as MaxCyte benefits from the expansion of programmes with licences covering clinical use, and a larger sales team. Commercial licenses, such as those with Precision BioSciences and CRISPR Therapeutics could further boost growth.
- **Valuation increased by 20p to 347p** We raise our valuation based on a SOTP methodology from £166m to £177m, following H118 results and CARMA progress. The company's cash position (including current investments) of $18.8m could allow operations into 2020, although we believe additional capital (equity, or commercial deal) will be needed to advance the IV version of MCY-M11 into the clinic.

Price (Sterling)	193p
Market Cap	£99m
Enterprise Value	£88m
Shares in issue	51.3m
12 month range	190p-284p
Free float	73%
Primary exchange	AIM London
Other exchanges	NA
Sector	Healthcare
Company Code	MXCT.L
Corporate client	Yes



Company description

MaxCyte uses its patented flow electroporation platform to transfect a wide array of cells. Revenues arise from sale and lease of equipment, disposables sales and licence fees; with an impressive client list. Additionally, a novel mRNA mediated CAR therapeutic, known as CARMA, is being explored in various cancers, including solid tumours.

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Investment case

A clear leader in a fast growing market

MaxCyte is a leader in the field of flow electroporation, with its instruments being broadly used by drug development companies, including all top 10, and 20 of the top 25 pharmaceutical companies. It markets four different systems (ATX, GT, STX and VLX instruments), which all use the same underlying electroporation technology, but target different market segments. These instruments are used to transfect cells: to assist drug discovery; manufacture products such as antibodies, vaccines and viral vectors; and develop cell therapies. Instrument sales also provided initial financing for the development of its proprietary CAR platform, CARMA. The first internal CARMA programme, MCY-M11 in ovarian cancer and peritoneal mesotheliomas, entered the clinic in October 2018. MaxCyte has raised a total of £30m since IPO in March 2016, which has funded expansion of its CARMA programme, and sales and marketing of its flow electroporation systems.

Valuation

Our model values MaxCyte at £177m, equivalent to 347p per share

Reflecting the inherent differences of the revenue-generating operations and the nascent clinical pipeline, we value MaxCyte using a sum-of-the-parts model with three-phase DCFs for the product and license fee operations, and a traditional rNPV for the development portfolio. We have updated our methodology for the valuation of the CARMA platform to base it on the value of MCY-M11, rather than on the milestones from five potential deals, now that there is better clarity on the development pathway. Our revised valuation, which continues to use conservative assumptions, values MaxCyte at £177m, or to 347p/share. This compares to the current market cap of £99m. and is solely supported by the sales generating operations, with the potential of the CARMA platform being essentially in for free, while the EV of other comparable CAR companies is over $200m.

Financials

Investments are yielding returns, and additional funds would clearly help

MaxCyte continues to invest in field scientists and sales staff to sustain its leading position, and in CARMA. Investments in the former, with expanded marketing activities, continues to drive double digit sales growth; we forecast an acceleration to c20% due to the increase in cell therapies approaching the clinic and extra marketing activities, which have already delivered several commercial licensing deals. Similarly, investment in the CARMA platform has led to the recent Phase I initiation with MCY-M11 (anti-mesothelin). MaxCyte has cash of $18.8m; and we would argue that additional funding (either via a deal or equity raise) would expedite execution of its development plans and should be embraced. The CAR field is a particularly fast-paced technology space, where advances in preclinical and clinical development are often rewarded with significant valuation uplifts.

Sensitivities

Operating in dynamic and competitive fields

MaxCyte's dual strategy with its fast-growing flow electroporation business means its risk profile is much lower than that of most biotech companies. But its prospects are still heavily linked to the results of the MCY-M11 Phase I trial, with initial results due in 2019. The quality of the data from this study, combined with advances with other competing CAR technologies, will determine the likelihood and size of any potential licensing deals for the CARMA technology. The other key issue determining MaxCyte's prospects is its ability to sustain its leading position in flow electroporation, with significant competition likely to come at some stage from companies such as Thermo Fisher Scientific and Lonza.

MaxCyte: Aiming to reap what it sows

MaxCyte remains the clear leader in the field of flow electroporation, a key enabling technology for many cell therapies. The company works with all top 10 pharmaceutical companies, and over 25 development projects with licences to use its technology in clinical trials, an increase of c60% over the last 12 months. Its broad portfolio of clinical, and more recently also commercial license agreements should underpin sustainable, and accelerating, sales growth. Coupled to this, progress of MaxCyte's proprietary CAR therapy, CARMA, could transform the prospects of the company over the next year or so. The first patient has recently been treated with MCY-M11, the lead CARMA product; the data from this trial will give the first true indication of the technology's potential. We have increased our valuation to by 20p to 347p/share.

MaxCyte's flow electroporation is effective, efficient, and versatile

MaxCyte's flow electroporation technology can transfect almost any mammalian cell with a wide variety of molecules, e.g. proteins, DNA, and mRNA, with minimal disruption to the cell. The patented technology is both highly efficient (90% to 95% effective cell loading commonplace), and very scalable ($2x10^{11}$ cells can be processed in less than 30 minutes in sterile and clinical conditions). The versatility and consistently high-performance of the platform mean that it is used widely in drug discovery and the manufacturing of many cell therapies in development.

First patient enrolled in CARMA proprietary clinical programme

While a key part of the business is collaborating with cell therapy companies, MaxCyte also has CARMA, its proprietary chimeric antigen receptor (CAR) therapy. CARMA is produced by transfecting unmodified blood cells with mRNA encoding a CAR, which can be done in a day with MaxCyte's patented technology, without a complex supply chain. CARMA has the potential to treat solid tumours, unlike current CAR-T technologies. A Phase I ovarian cancer and peritoneal mesothelioma study with the lead CARMA therapy, MCY-M11, initiated in October. Data from the trial will be reported from H119, providing an indication of the safety and efficacy profile of MCY-M11, and potential of CARMA products.

Platform is used extensively across cell therapy field

The strength of MaxCyte's flow electroporation technology means it has become the partner of choice for companies developing advanced cell therapies requiring non-viral modification of cells *ex vivo*. This is particularly the case in immuno-oncology and gene editing (including CRISPR-Cas9). MaxCyte has licenced the use of its technology to various companies, eg CRISPR Therapeutics, Sangamo, Kite (Gilead), Precision BioSciences, TMunity. There are now >55 programmes in development, c 10 more than at H117; >25 programmes (+c60% over the year to June 2018) have clinical licences, with cumulative potential clinical and approval milestones from announced commercial deals is currently >$250m.

Service revenues set to continue strong organic growth

Greater use of MaxCyte's instruments in cell therapies, as well as in drug discovery and bio-manufacturing, is driving sustained double-digit growth of the core service business. Sales have grown at a CAGR of 19.7% to $14m during the four years to FY17. Revenue growth in FY17 and H118 slowed slightly to 14% and 12%, respectively; but we expect this to accelerate back to c 20% for FY18 and the foreseeable future, as sales benefit from the increase in clinical stage licences for cell therapies, expansion of its sales teams, and rapid growth and investment targeted at key markets. There is the prospect of more programmes requiring commercial licences too, which could significantly boost sales growth.

The key to next-generation therapies

Cell therapies are finally fulfilling their long-promised potential

After many years of discussing the tremendous potential of cell therapies to treat a broad range of indications, from cancer to chronic limb ischaemia to heart failure, they became a reality in 2018 with the approval of the CAR-T (Chimeric Antigen Receptor T-cell) therapies, Novartis' Kymriah and Gilead's Yescarta for certain B-cell cancers. Key to the potency of these therapies is the modification of T-cells so that they express the CAR and become programmed to destroy any cell expressing the CD19 protein. Similarly, the activity of many cell therapies depends on the cells being modified.

In the case of currently approved CAR-T therapies, they are modified using a viral vector (a lentivirus) to insert the gene encoding the CAR into the genome of the T-cells. However, this approach is costly, technically challenging, and there are limitations on what can be transfected[1] into a cell. In addition, accessing viral manufacturing capacity is increasingly becoming a major bottleneck. If a viral method is inappropriate, there are two main non-viral methods to transfect a cell:

- **Biochemical**: using reagents such as calcium phosphate, lipofection, DEAE-dextran, and dendrimers; and
- **Physical:** electroporation, flow electroporation, nucleofection, and other (including gene gun, sonoporation, magnetofection, and optoinjection).

Cell modification is complex, and method employed depends on use

The optimum way of transfecting a cell will depend on the cell type and the desired modification. Chemical methods are often used in academic research, where the low relative cost and flexibility are key factors that often overcome other limitations, and where the challenges of biochemical methods (lack of consistency and scalability) are less important. Physical methods have come to the fore more recently, with electroporation[2] now the most widely used. Ideally, the method should have high transfection efficiency, low cell toxicity, minimal effects on normal cell physiology, be easy to use, and be reproducible.

Over the past 20 years, MaxCyte has established itself as the sole supplier of flow electroporation instruments to the pharmaceutical and biotechnology industries. Its patented technology can effectively transfect almost any living cell with a wide variety of molecules and genetic material in a consistent, scalable and efficient way, as illustrated in Exhibit 1. MaxCyte's validated and differentiated approach to cell engineering has addressed many of the key challenges (Exhibit 2), and the experiences gained have resulted in a system that is robust, reliable, and scalable; importantly for commercial applications, it is also highly reproducible.

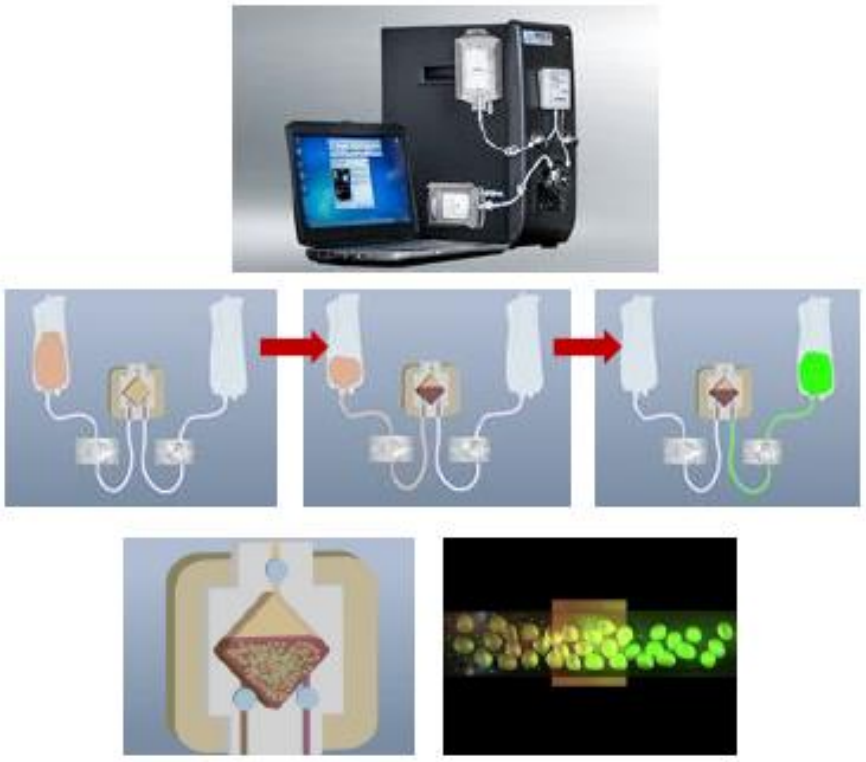
Three key systems address the various main market segments

MaxCyte's instrument range consists of four models: the **STX** addresses the core research market segment for cost-effective assay development, high throughput screening (HTS), high content screening (HCS), gram scale protein production, and other applications; the **VLX** offers similar versatility and ease of use but the

[1] Transfection refers to the modification of biological cells through introduction or transfer of selected material, such as DNA or RNA, into the cell. The technological advances of the past decade have resulted in a seismic shift in cell-based research activities, leading to the developments seen in immune-based cancer treatments.
[2] Electroporation is the application of an electric field to cells to temporarily increase the permeability of the cell membrane, allowing the passage of larger molecules than would normally be allowed to enter the cell.

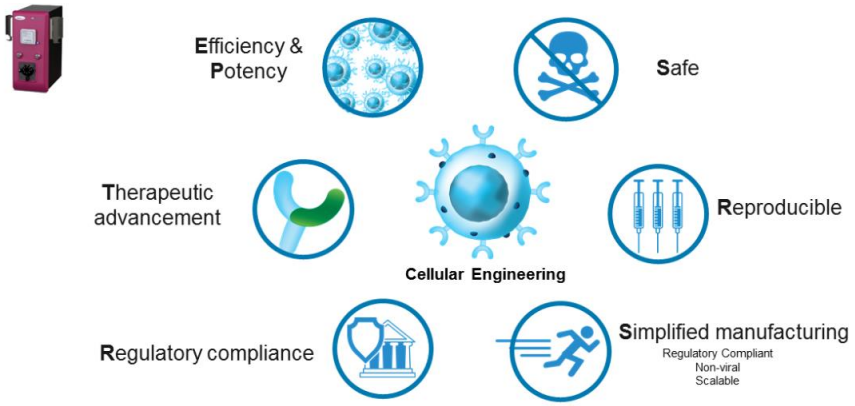
capacity increases from $1x10^{10}$ cells per cycle to $2x10^{11}$ cells and is particularly suited to higher production needs (eg vaccines and viral vectors); the GT is of similar capacity to the STX but is cGMP compliant and targets the specific needs of those working on the preclinical, clinical development and potential commercial needs of cell-based therapies. The ATX is used for smaller scale/or earlier stage applications; it uses non-flow electroporation but delivers the same high level of performance.

Exhibit 1: A diagram illustrating MaxCyte's flow electroporation process



Source: MaxCyte

Exhibit 2: Solving challenges critical to industry success



Source: MaxCyte

Three different, but complementary, strategic approaches…

The broad applicability of MaxCyte's electroporation technology has led to the development of a three-pronged strategy (Exhibit 3 overleaf). In drug discovery, its instruments can be used to facilitate the process, eg low cost and rapid bio-manufacturing. In cell therapy, MaxCyte works particularly closely with partners

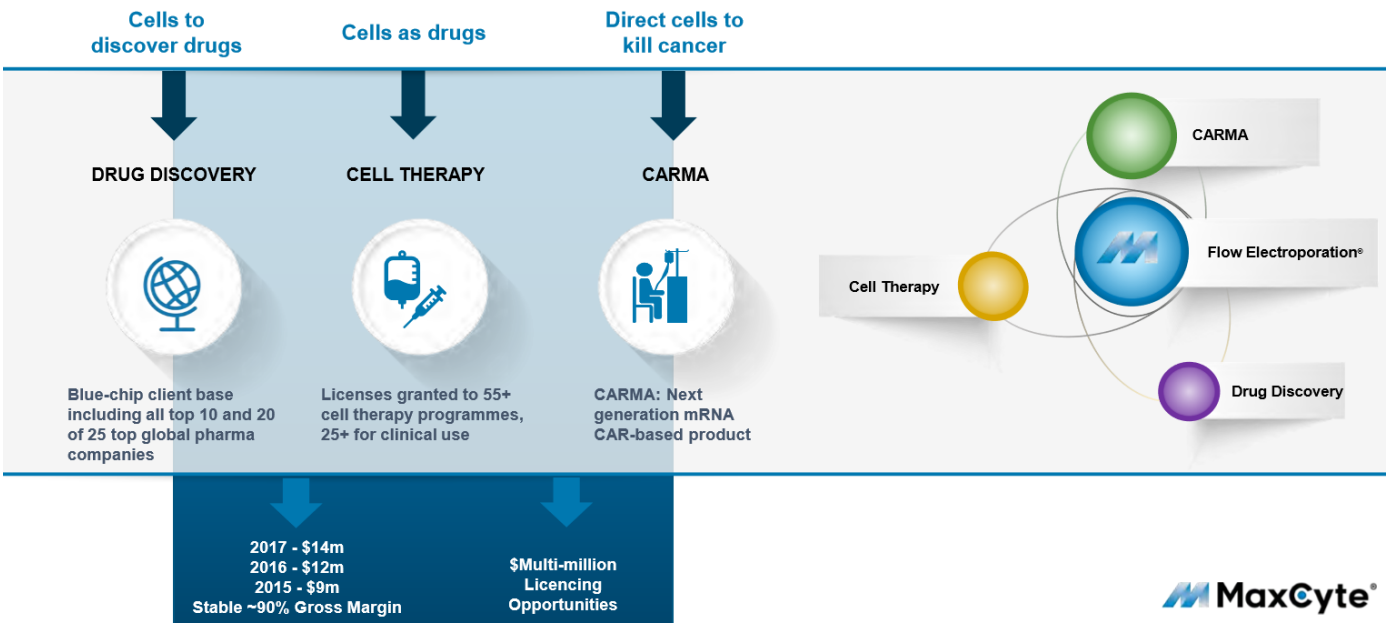
to enable the manufacturing of the partner's cell-based therapeutic. Finally, CARMA is MaxCyte's wholly-owned CAR therapy, which has just reached an important developmental milestone with the treatment of the first person with a CARMA therapy in the current Phase I study with MCY-M11.

The three business lines have very different risk and return profiles. The CARMA platform has greatest potential value, as highlighted by the $11.9bn acquisition of Kite Pharma by Gilead for its CAR-T technology in 2017, but there is significant risk associated with the programme. In contrast, there is less upside with the drug discovery business, but relatively limited risk given the breadth and quality of its client base. Cell therapy sits between the two, where MaxCyte can earn significant revenues from commercial licenses (7-8 figure milestones and sales-based payments), as well as disposable sales per patient treated; however, these revenues are exposed to drug development and commercialisation risks.

...with each making a valuable contribution to the equity story

It is also important to note that the three business lines, which will be discussed in more detail later, complement each other. The technical innovations and learnings that MaxCyte makes in any one activity will typically enhance the value of the other two.

Exhibit 3: MaxCyte's three-part business model



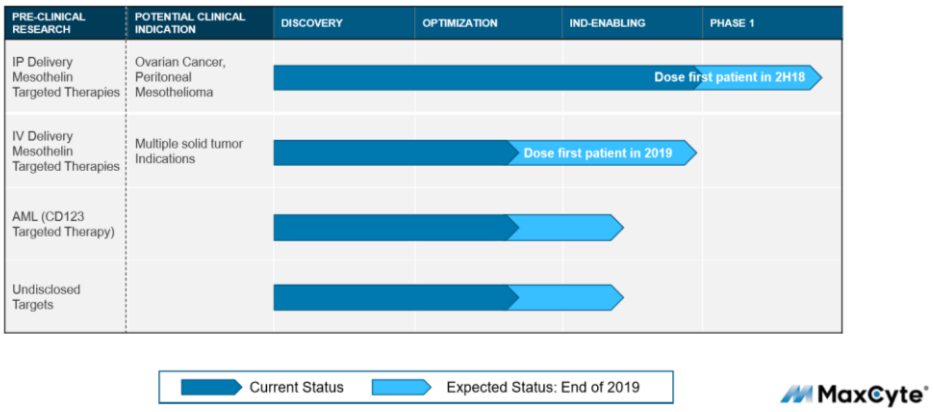
Source: MaxCyte

Moving forward with the CARMA platform

CARMA is a proprietary technology platform, with significant potential advantages over CAR-T therapies

The CARMA technology platform could generate the largest potential upside to MaxCyte among its key assets. It is wholly owned and was internally developed to capitalise on the company's extensive cell therapy and transfection expertise. CARMA is a novel mRNA-mediated CAR technology that could provide fewer off-tumour side-effects and has a simpler, more rapid, and less costly production system than current CAR-T approaches. Exhibit 4 provides a status overview of the CARMA pipeline, which targets both solid and haematological cancers.

Exhibit 4: Wholly-owned CARMA pipeline

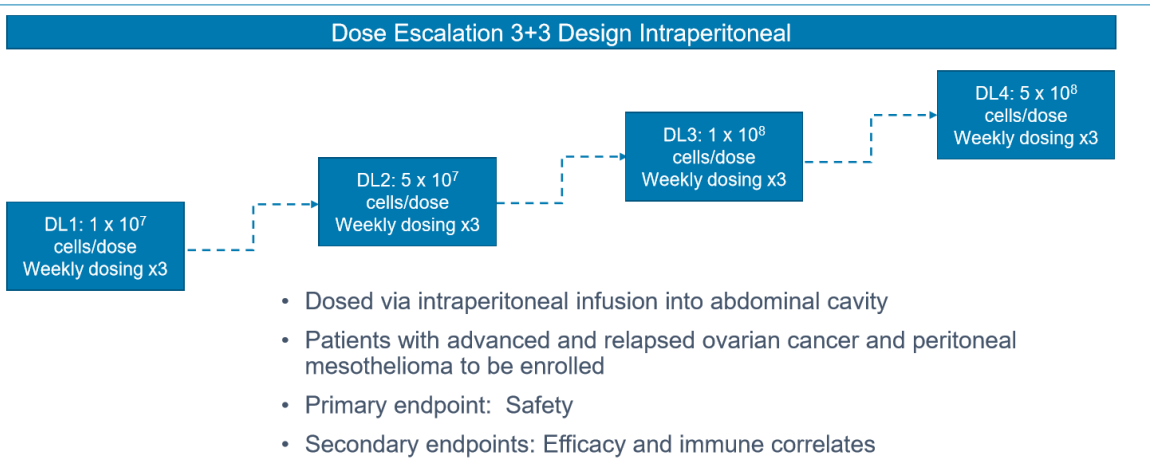


Source: MaxCyte

MCY-M11: first solid tumour Phase I underway

In October 2018, Maxcyte dosed the first patient in a Phase I trial (Exhibit 5) of its lead CARMA programme, MCY-M11 (anti-mesothelin, CARMA-hMeso), following IND clearance in July 2018. The Phase I trial is a dose-escalation study (3+3 design) in c15 patients with ovarian cancer or peritoneal mesothelioma, who will receive three weekly doses of MCY-M11 delivered intraperitoneally, without any preconditioning treatment (eg cyclophosphamide or fludarabine). It is being conducted at National Cancer Institute, National Institutes of Health in Maryland, and Washington University in St. Louis in Missouri, with a primary endpoint of safety, and with efficacy and the analysis of biomarkers as secondary endpoints.

Exhibit 5: MCY-M11 Phase I clinical trial design



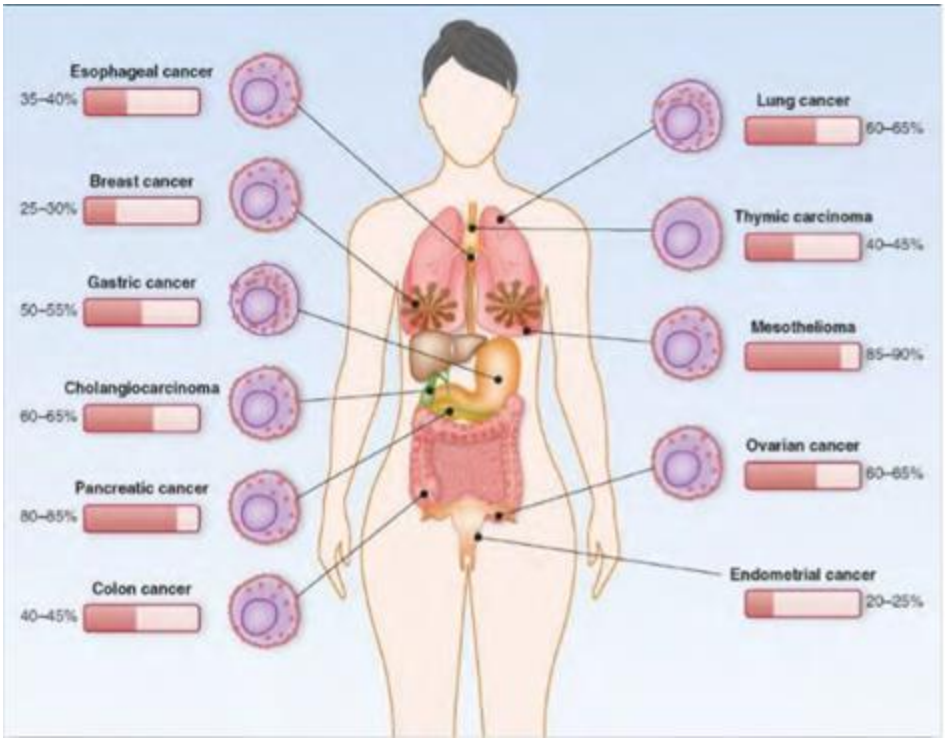
Source: MaxCyte

Initial data from the study is expected in early 2019, but a better indication of the potential of MCY-M11 will probably become apparent later in the year, once patients have received the higher doses. In addition, a second CARMA therapy, an intravenous version of MCY-M11, should enter the clinic in H219.

Clinical trial to confirm CARMA potential

A key goal of the MCY-M11 Phase I study is to confirm the potential of CARMA, particularly in solid tumours where virus-modified CARs are challenged by the need for complex and unproven toxicity mitigating approaches. It will provide the first indication in patients whether CARMA therapies can have a significant anti-tumour effect, while validating the ease of manufacturing, and the potential ability to avoid causing significant on-target/off-tumour toxicities. MCY-M11 targets a widely expressed protein, mesothelin, which is expressed at normal levels on mesothelial cells, but at high levels on various tumours, including ovarian cancer (Exhibit 6).

Exhibit 6: Frequency and distribution pattern of mesothelin in solid tumours



Source: MaxCyte, adapted from Cancer Discovery 2016 (Feb): 6(2) 133-46; Pastan PNAS (1996)

The trial design highlights two important features of CARMA therapy, which are points of differentiation over approved CAR-T treatments.

- **Dose response:** The dose-escalation should allow MaxCyte to identify the optimal dose of MCY-M11, considering efficacy, safety, and commercial aspects (eg the number of doses produced from a single apheresis). A dose response has been seen in preclinical studies and supports the view that on-target/off-tumour effects should be manageable.

CARMA cells effectively act as antibodies conjugated to cytotoxic T-cells

CARMA cells only survive transiently, whereas CAR-T cells become engrafted in the recipient so there is not a clear dose response. Therefore, there are more parallels between CARMA therapy and an armed antibody (CARMA cells are effectively antibodies conjugated to cytotoxic T-cells) approach than with a CAR-T therapy.

- **No pre-conditioning treatment**: there are significant toxicities associated with the use of preconditioning regimes (eg cyclophosamide or fludarabine), which are common with CAR-T therapies to enable the CAR-T cells to engraft.

Features of CARMA therapy, including the potential for increased safety; its applicability to solid tumours as well as haematological cancers; and the reduced complexity, lower cost, flexibility and scalability of the manufacturing process, are explored in greater detail below.

CARMA: a potential edge over CAR-T

Taps into the exciting field of CAR-T therapies

A number of CAR-T[3] therapies have shown remarkable efficacy in the clinic, although there are significant adverse events, including cytokine release syndrome and neurotoxicity. This has elicited widespread excitement in the medical and investment communities as their potential could herald a new era in cancer treatment; yet their current applicability beyond a relatively small subset of blood cancers remains a source of major frustration[4]. A variety of approaches have been tried in solid tumours but with limited success to date. This reflects the challenges that remain in target selection (a lack of truly unique tumour-associated antigens), accessibility (inefficient homing of T-cells into the tumour site), and finding pathways to overcome active immune suppression within the tumour microenvironment.

Exquisite activity, but extensive on-target/off-tumour side effects

The clinical success seen in B-cell haematological malignancies reflects the exquisite nature of the CD19 antigen. Most B-cell malignancies, as well as normal B cells, express the CD19 antigen but this antigen is absent from other cell types, making it an attractive therapeutic target. Clearly accessibility and the tumour microenvironment are less of an issue in blood cancers, but the long persistence of effect also causes B-cell aplasia (increasing infection risks and requiring costly long-term plasma infusions). B-cell aplasia (elimination of all a patient's B-cells) is a consequence of the effective targeting of the CD19 antigen and is known as an on-target/off-tumour side-effect.

Despite extensive efforts, solid tumours have remained elusive

Solid tumour antigens have the potential to be immunogenic, but as tumours arise from the individual's own cells, only mutated proteins or proteins with altered translational processing will be seen as foreign by the immune system. Antigens

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[3] CAR-T refers to techniques that genetically engineer a patient's own T-cells (or T-lymphocytes), a type of white blood cell that orchestrates the body's immune response, so it can express specific proteins called Chimeric Antigen Receptors (CARs) that enable the T-cells to identify and help destroy cancerous cells. The T-cells are harvested and modified *ex-vivo* typically using lentivirus then returned to the patient. This model of delivery is very expensive and time consuming and is completely different from existing pharmaceutical approaches since it requires the creation of a highly personalised product for each patient and the lengthy manufacturing associated with lentivirus approaches.

[4] Whilst CAR-Ts have shown amazing efficacy in B-cell malignancies, their use in other cancers has been limited, in part, by antigen-specific toxicities and life-threatening CRS (cytokine release syndromes). Researchers globally are evaluating a variety of complex methods to overcome these, including novel antigen cocktails that only activate for a specific tumour site, introducing "suicide switches", co-administration with other agents (eg IL-6R blockers), and tailoring the T-cells' CAR expression to suit the particular tumour type.

that are simply up-regulated or over-expressed (so called self-antigens) will not necessarily induce a functional immune response against the tumour.

CARMA offers promising activity...

The CARMA platform allows for the transient expression of the selected antigen complex, with the ability to control the timing and clinical effect with a degree of flexibility. This allows the treatment of the full range of haematological malignancies and solid tumours as the potentially limiting issue of on-target/off-tumour toxicities can be managed by varying the dosing (number of cells per dose and frequency of dosing) to deliver the optimal balance of targeted anti-tumour activity with tolerable toxicity. Whilst this would be a worthwhile advantage in treating B cell malignancies, the true value would be in solid tumours where limiting on-target/off-tumour toxicities could be a critical determinant of success.

... and overcomes a number of production issues

Another key issue affecting the wider adoption of CAR T-cell therapy will be how to roll it out at scale; new production techniques and tailored supply chains are required. Currently the system, both for autologous (patient-derived) and allogeneic (donor-derived) cells is complex, time consuming, and expensive (see Exhibit 7). The problems of industrialising these processes are many; producing material at a commercially viable scale is complex, and few systems reliably and consistently provide adequate yield, scalability, and potency.

Commercial manufacture is currently a major bottleneck

The existing manufacturing process takes between 7 and 15 days and is estimated to cost $200k-$450k per patient. Substantial efforts are being made to automate as many of the procedures as possible to reduce variability, increase reproducibility, and lower costs. Nonetheless, the challenges to successfully producing commercial grade material for use in a variety of clinical settings are manifold and remain daunting.

Exhibit 7: Key steps in producing an autologous virus-based CAR-T therapy

The raw material is blood cells, which are transformed in a 5-step process:

- **Step 1: Apheresis** consists of extracting the T-cells from among the Peripheral Blood Mononuclear Cells (PBMC) of the blood and isolating with a cGMP compliant process. Then transportation to the cell processing site.
- **Step 2: Selection and activation of T-cells** through stimulation of TCR (T-Cell Receptor) and Co-stimulation receptor (eg CD3 and CD28) to transform them into a Cytotoxic T-Cell (CD8+).
- **Step 3: Transfection.** Once a T-cell is activated, the CAR needs to be expressed by the cell to recognize the tumours. This requires the insertion of a gene or other component via a vector (currently this is typically via a Lentivirus). In the case of allogeneic cells, the immunogenicity is reduced at this step (eg through TCR knock-out).
- **Step 4: T-Cell expansion.** Needs to strike the right time balance for proliferating the culture. The period has to be long enough for good CAR insertion, but not too long as over time cells begin to lose their function.
- **Step 5: Conservation** and **administration.** Cells are purified, processed and cryo-preserved before being transported back for infusion into the patient.

The process takes between 7 and 15 days and is currently very labour intensive.

Source: Trinity Delta and MaxCyte Note: The CARMA approach significantly simplifies the process as indicated in Exhibit 8.

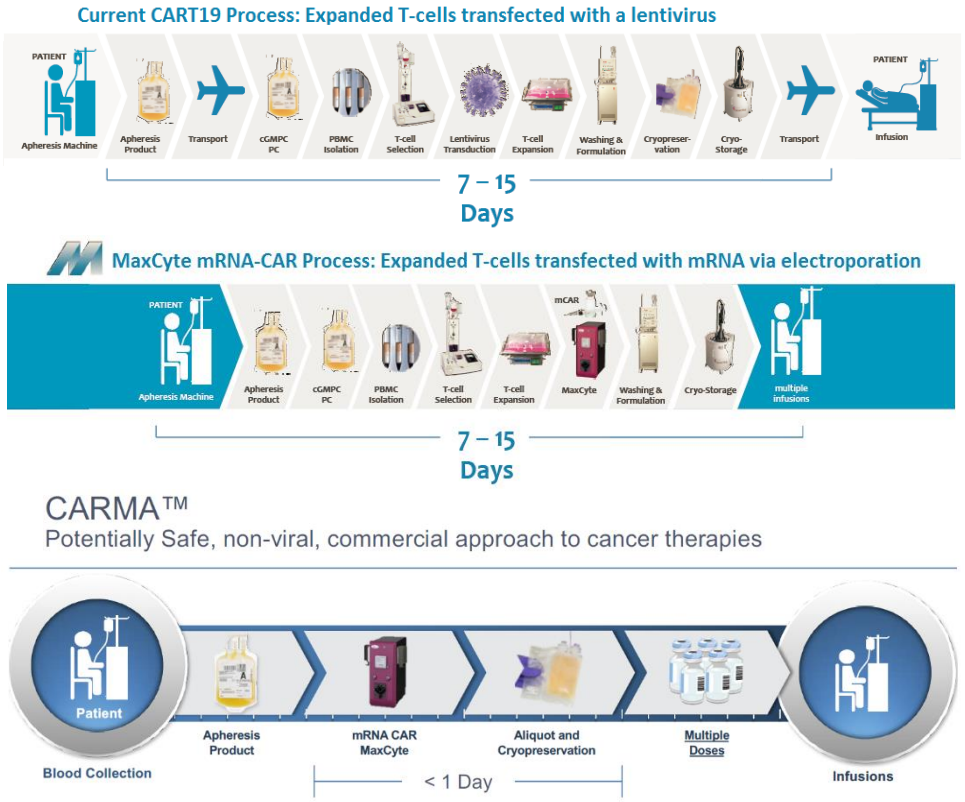
Supply chain benefits

CARMA could reduce process time from 1-2 weeks to a single day

The CARMA platform can potentially offer several supply chain benefits over the lentiviral vector systems and mRNA CAR. The current process (Exhibit 7) using lentivirus transfection is complex and time-consuming, requiring the cells collected during apheresis to be transported to a central facility (Exhibit 8). The mRNA-CAR process used by the University of Pennsylvania and NUS with MaxCyte's flow electroporation is much simpler and can be completely conducted in a hospital; however, it still requires the expansion of the T-cells and hence still takes one-to-two weeks.

In comparison, MaxCyte's CARMA process is even simpler, with fresh blood cells (Peripheral Blood Mononuclear Cells, PBMCs) transfected rather than only expanded T-cells, and avoiding the time-consuming expansion step. This means that the CARMA process can be carried out in a single day, and this has been validated during the treatment of the first patient in the MCY-M11 Phase I study.

Exhibit 8: A comparison lentiviral CAR-T, mRNA CAR and CARMA processes



Source: MaxCyte

Early clinical studies confirm potential of mRNA CAR-T

MaxCyte originally got involved in the CAR-T field through two notable collaborations with world leaders in the CAR field. These are with Dr Carl June of the University of Pennsylvania and Dr Dario Campana originally of St. Jude's Children's Research Hospital and now with the National University of Singapore. The goal of these alliances was to develop a non-viral and safer approach to produce CAR-T therapies capable of addressing more tumour types and reducing on-target/off-tumour toxicities.

Preclinical and early clinical trials confirm potential of mRNA CAR-T approach

To date over 20 patients have been treated in nine independent clinical trials (seven at University of Pennsylvania and two at National University of Singapore

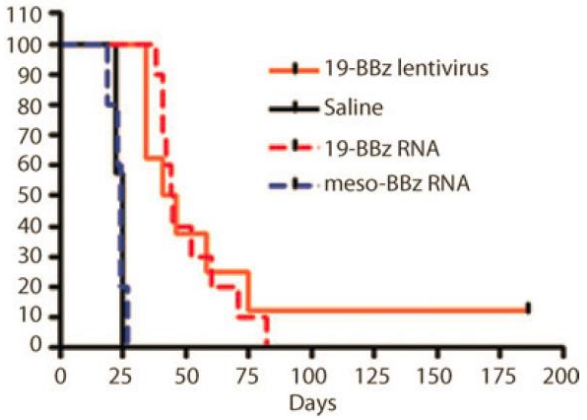
[NUS]) using mRNA and MaxCyte's technology to engineer expanded T-cells to express CAR, which have confirmed the potential of the approach. In a small clinical trial with 14 patients conducted by the University of Pennsylvania with anti-mesothelin CAR-T therapy in mesothelioma and pancreatic cancer, the treatment was well tolerated without dose-limiting toxicity and one patient achieved a partial response and six patients experienced stable disease (Source: J. Clin. Oncol. 33, 2015). Other antigen targets of mRNA CAR-T therapies that have been studied include GD-2 and c-Met in solid tumours, and CD-19 and CD123 in haematological cancers.

Preclinical and early clinical trials confirm potential of mRNA CAR-T approach

The initial results from these admittedly early trials also suggest that both on-target/off-tumour toxicities and CRS (cytokine release syndromes) can be contained. However, Janos Tanyi from the University of Pennsylvania has said that his group at the University would be concentrating its efforts on the lentiviral approach as "the antitumor effect was very limited" with the mRNA CAR-T cell only detectable for one to two days with a dose of 10^8 cells. MaxCyte disagrees with this view, citing the findings of Carl June's group who found that they detected mRNA CAR-T cells up to seven days after administration with 10^9 cells. There is also preclinical data suggesting that mRNA CAR-T cells can be as potent as lentiviral CAR-T cells (Exhibit 9).

Exhibit 9: Anti-CD19 mRNA CAR-T have similar activity to anti-CD19 lentiviral CAR-T therapy in mice

Early studies support view that further trials are warranted



Source: Barrett DM et al, Human Gene Therapy, 22, 1575-86, December 2011

Preclinical results suggest simplified process is as effective

When MaxCyte was studying mRNA CAR using expanded T-cells, it discovered that it could significantly simplify the process by transfecting freshly isolated PBMCs (Peripheral Blood Mononuclear Cells) while producing cells with the same level of anti-tumour activity. Consequently, MaxCyte decided to invest the profits from the sale of the flow electroporation instruments into its proprietary CARMA platform. We also note the potential for the CARMA approach to have enhanced potency because the cell product contains multiple immune cell types (eg. T and NK cells), rather than just T-cells. Also, the cells are fresh, and have not gone through the expansion step required with viral approaches, which may change or weaken their effectiveness.

Partnering strategy for CARMA

MaxCyte does not intend to become a drug development company and conduct advanced clinical trials with CARMA. Instead it plans to use the data from the Phase I/II studies, assuming the data are positive and confirm the potential of CARMA, to find a partner(s) to develop the platform further with Phase II/III

studies and against other targets. Ideally, the strength of the data from the first indication will be such that it drives demand for the preclinical assets without the need for clinical data.

Potential for major licensing deals

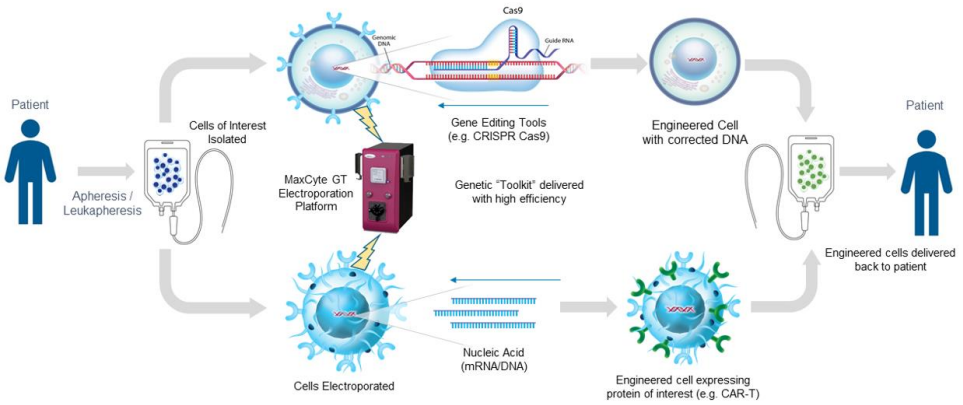
The potential value of such deals is high, but difficult to estimate. Given the interest in CAR-T and other cellular therapies, a deal size of >$150m in milestones and royalties per programme/target appears realistic. Deal timing is understandably uncertain, but it is most likely that the first deal is struck in 2020.

Partnered programmes in cell therapy

Consistency and versatility make MaxCyte's systems key enablers of cell therapies

Beyond CARMA, MaxCyte targets being the partner of choice for companies developing cell therapies that need *ex vivo* (outside the body) modifications, irrespective of the type of cell engineering (Exhibit 10). The strength of the platform, which can load cells consistently (even when transfecting large molecules of up to 500kDa) and still maintaining cell viability (c 95%) means that many companies have already chosen MaxCyte as a preferred partner.

Exhibit 10: MaxCyte's technology at the forefront of cell therapy revolution



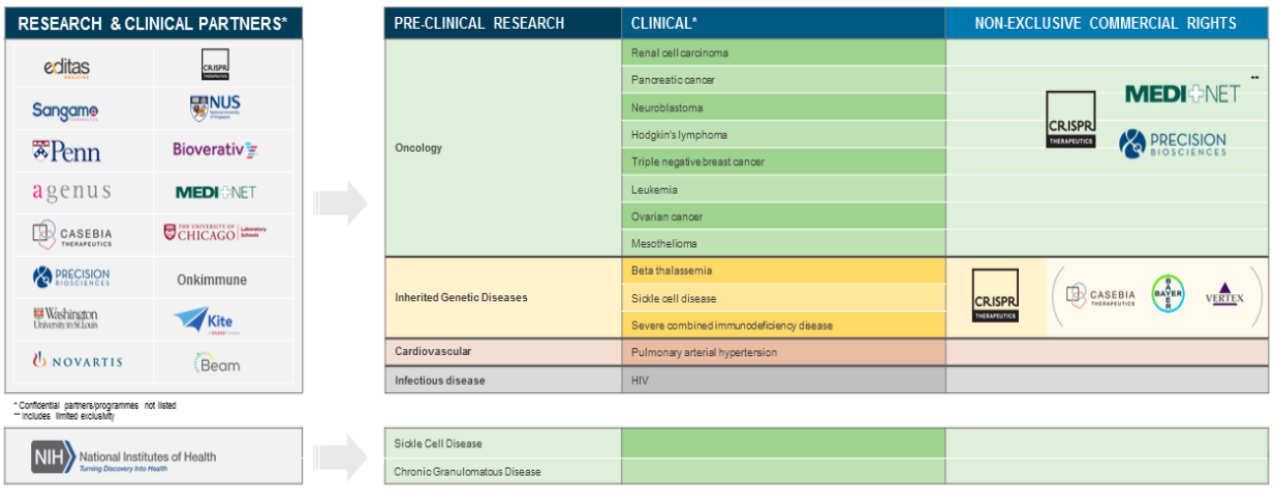
Source: MaxCyte

Leading academic institutions and biotech companies are using the GT

The number of cell therapy programmes using MaxCyte's system continues to increase steadily, and there are currently over 55 such licensed programmes in place with a variety of pharmaceutical, biotechnology and academic institutions (Exhibits 11 and 12), including:

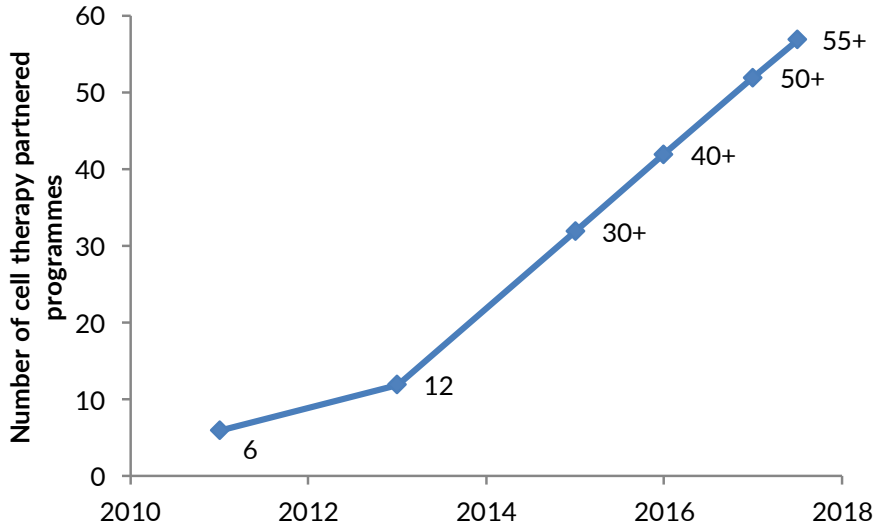
- Gene-editing companies, such as CRISPR Therapeutics, Editas and Sangamo;
- Other cell therapy companies, such as Kite and Precision BioSciences; and
- Academic institutions, such as University of Pennsylvania, National University Singapore, Washington University at St Louis, and US National Institutes of Health.

Exhibit 11: 55+ non-exclusive, non-CARMA drug development partnerships



Source: MaxCyte

Exhibit 12: Number of partnered programmes in place



Source: MaxCyte, Trinity Delta

Further clinical and commercial licenses anticipated

Number of partnered cell therapy programmes continues to rise rapidly

Of the 55+ licensed programmes, over 25 of them are licensed for the clinical stages of development, up from over 15 (c+60%) a year ago. The advancing development of cell therapy programmes using MaxCyte's technology suggests that momentum in the number of licenses for clinical use will continue, and over time an increasing number of commercial licenses will be sought by partners. The growing and maturing license base will underpin robust future revenue growth; and is testament to MaxCyte's leading market position and its in-depth scientific and regulatory understanding of cell therapies across the value chain.

At present, Medinet is commercially marketing in Japan a personalised dendritic cell treatment for oncology, which is manufactured using MaxCyte's GT instrument. MaxCyte recently granted two other notable non-exclusive commercial licenses, with CRISPR Therapeutics and with Precision BioSciences, which build on existing research and clinical license agreements.

First commercial licenses signed for CRISPR-based therapies, and also novel allogeneic approaches

In March 2017, MaxCyte signed an agreement covering the commercial use of its systems with CRISPR Therapeutics and Casebia (the JV between CRISPR Therapeutics and Bayer) for two preclinical CRISPR-based therapeutics for haemoglobin-related diseases and SCID (severe combined immunodeficiency). This agreement with CRISPR Therapeutics was expanded in November 2018 to provide a non-exclusive commercial license covering the development of CRISPR/Cas9-based therapies in immuno-oncology. CRISPR Therapeutics currently has three preclinical allogenic immuno-oncology assets. The most advanced, CTX110 (anti-CD19 for various B-cell malignancies), is expected to enter the clinic in H119. CTX120 (anti-BCMA for multiple myeloma) is also in IND-enabling studies, with CTX130 (anti-CD70) at an earlier stage of preclinical development for both solid tumours and hematologic malignancies.

The non-exclusive clinical and commercial license with Precision BioSciences, also announced in November 2018, couples MaxCyte's flow electroporation technology with Precision's proprietary ARCUS genome-editing technology to develop undisclosed next-generation allogeneic T-cell immunotherapies for

oncology. The key attraction to Precision was the complementarity of both technologies in preserving cell quality and maximising overall yield.

A case study in CRISPR

The capabilities of MaxCyte's technology are highlighted in the field of CRISPR-Cas9-based therapies, which require the efficient and consistent transfection of both oligonucleotides and RNAs for CRISPR into specific cells in a reproducible manner. MaxCyte presented a poster at the American Society of Gene and Cell Therapy Annual Meeting (ASGCT) in May, which suggested that the combination of CRISPR and MaxCyte's flow electroporation technology could be used to treat sickle cell disease (SCD) by correcting the single mutation in the haemoglobin gene *ex vivo*. MaxCyte was able in the preclinical studies to correct the haemoglobin gene in CD34+ haemopoietic stem cells (HSC), such that when they differentiated into erythrocytes (red blood cells), 60% of the resultant cells expressed normal, wild-type haemoglobin, and sickle haemoglobin production fell from 100% to 20%.

A new CRADA agreement will advance a gene-correction therapy towards clinical development

The progress with the SCD project led to MaxCyte entering into a Cooperative Research and Development Agreement (CRADA) with the US National Institutes of Health (NIH) in June 2018. During the collaboration, MaxCyte will be collaborating with the National Heart, Lung, and Blood Institute (NHLBI) to continue the preclinical development of the therapy. This is MaxCyte's second CRADA; in June 2017 it formed one with the NIH's National Institute of Allergy and Infectious Diseases (NIAID) to advance the programme for the treatment of chronic granulomatous disease (CGD), which causes immunodeficiency in c1 in 250,000 people because of a mutation in CYBB gene.

It is worth noting that MaxCyte is a leader in the field of CRISPR technology, as well as in flow electroporation. In both SCD and CGD, MaxCyte has shown that its systems can be used in gene correction as well as gene knock-outs. Most gene editing companies are generally focused on the lower technical challenge of developing therapies that simply knock out a faulty gene.

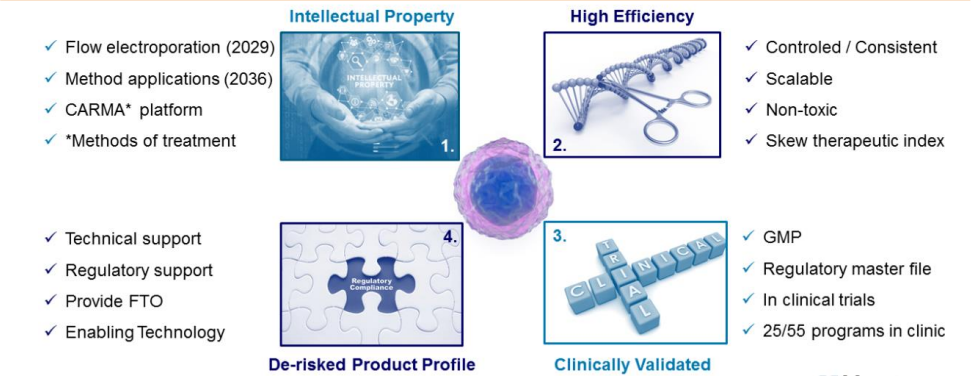
The value proposition

The FDA Master File simplifies the regulatory process for partners

MaxCyte primarily licenses the use of its GT instruments to cell therapy companies. Exhibit 13 provides an overview of the value proposition for these partners. The GT devices are closed sterile systems that are cGMP compliant, with, importantly, a Master File[5] lodged with the FDA. The Master File is a confidential dossier that effectively details, and validates, all the key parameters and processes employed. Unlike the STX and VLX instruments, the GT is leased to customers with an appropriate licence for use in narrowly defined fields. These are typically for non-exclusive, and initially, non-commercial use, and describe the distinct cell types, the target indications, and the class of molecules employed.

[5] An FDA Master File for biologic project is a confidential dossier that contains full information about the facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drug products. It is used to help prove the quality, safety and efficacy of a medicinal product ahead obtaining an Investigational New Drug Application (IND) and a Biologic License Application (BLA).

Exhibit 13: MaxCyte's value proposition to partners



Source: MaxCyte

Fees charged can vary widely; reflecting factors such as the nature of the client (academic vs commercial), the breadth of indications studied, and the stage of the programme (research vs clinical vs commercial). A license allows a customer to reference the FDA Master File, simplifying and expediting clinical planning.

Each lease is structured to the partner's needs but will normally follow the approach below:

- an initial research lease that allows sufficient support to explore a potential application in a defined area; which
- if the programme shows sufficient promise to enter development then a clinical lease is required (which allows access to the Master File to support the IND); and,
- assuming a successful proof of concept (potentially at Phase I/II or Phase IIa), then a broader commercial lease will be negotiated.

As indicated by the deal with CRISPR Therapeutics/Casebia, timings for the transitions clearly vary according to the programmes but, using industry averages, we would normally expect 6 to 18 months for a research lease and 2 to 5 years for a clinical lease, with a commercial lease being agreed during clinical development. Interestingly, however, the commercial licenses granted to date appear to have been secured well-ahead of potential commercialisation as partners lock-in their access to MaxCyte's technology. Therefore commercial license timing may be influenced by the progress of clinical development or by the licensee's advancement towards partnership with large pharma.

Deal terms are not disclosed but we, conservatively, estimate them to be worth $10m each

None of the terms of any of MaxCyte's deals have been disclosed, although cumulative potential clinical and approval milestones from announced commercial deals for use of MaxCyte's technology are in excess of $250m. We estimate that fees for later programmes are around $250,000 pa, with further revenues also arising from the disposable processing assemblies (estimated at around $20,000 per instrument per year, though they are likely to vary considerably) and clinical milestones. As these programmes progress through clinical development, and approach commercialisation, the licensing deals are expected to broaden to include additional fees, including upfront license fees, milestone payments (starting from six-figure to low seven-figures for early clinical milestones, with larger amounts for later-stages) and/or royalties on eventual product sales. Although the amounts will likely reflect commercial factors (e.g. indication market size, manufacturing complexity, treatment pricing, etc), we estimate that the deals are valued at c$10m each per therapeutic product on a risk adjusted NPV basis.

Drug discovery and bio-manufacturing

STX model is highly versatile, easy to use, and generates reproducible results

There are a wide variety of applications for MaxCyte's systems during the drug discovery process. This is why all of the top 10 pharmaceutical companies, and 20 of the top 25 companies, are clients of MaxCyte. The three systems that the company sells into this market are the STX, ATX and VLX.

The STX offers an ideal blend of flexibility and performance in a cost-effective package. For instance, cells can be transfected to produce a variety of assays (including ion channel, GPCRs, reporter genes, and siRNA based) that are comparable to stable cell lines in terms of quality and performance, but in a fraction of the time and in physiologically-relevant cells. The STX can be used to manufacture small volumes (gram scale for preclinical studies) of difficult to produce compounds, such as multi-valent antibodies, which is usually all that is required for research purposes.

The VLX can be used to produce multi-gram quantities of proteins, antibodies, viral vectors, and recombinant vaccines to cGMP standards. It is capable of transiently transfecting extremely large volumes of cells (up to $2x10^{11}$ cells in around 30 minutes), which can result in significant savings (at least an order of magnitude) compared to other transfection methods. Despite this, it is still a compact unit and simple to operate. The VLX can also significantly delay the need to establish a stable cell line for bio-manufacturing (see poster presented at Peptalk in January 2018). The VLX can be used to manufacture the biologic in a couple of weeks, in comparison it takes several months to establish a stable cell line, thereby saving a considerable amount of time and money during early development.

North American and European sales teams bolstered since IPO

Both the STX and VLX, and their respective disposable processing assemblies, are sold primarily to biotechnology and pharmaceutical companies by a small sales team directly in North America and Europe, and through distributors in other markets. Historically little resource was available to support the marketing effort but since the IPO in 2016 the sales team has doubled in size and we expect it will grow steadily as the opportunities for MaxCyte continue to expand.

One area of growth for MaxCyte is currently bio-manufacturing. The new biologics in development are more potent, so that smaller quantities of drug product are required for preclinical development, which can easily be manufactured by the VLX. At the same time, the drug discovery field is so competitive that the time saved by not having to make a stable cell line, could give a company a significant advantage over a rival.

Installed base and consumables sold per instrument growing

The average price of the STX is around $110,000, and we estimate that each one generates on average more than $30,000 per annum in consumables sold per instrument. The installed base of instruments is now more than 200 instruments. The VLX is priced at around $450,000 and, as yet, only a few have been sold. The selling cycle for the STX tends to be quite short (around 3-9 months from lead identification to sale), with the VLX being understandably longer. MaxCyte has a broad and robust sales base, with no customer accounting for more than 10% of revenues in 2017.

Well-positioned in an attractive market

MaxCyte is the dominant flow electroporation company

MaxCyte's instruments address a well-defined need in a large market segment. The Markets and Markets report (June 2015) on Transfection Reagents and Equipment estimates this to be worth $676.8m in 2015 and expects it to grow by 7.2% CAGR to $957.9m in 2020. By usage North America is the largest, closely followed by Europe, and then Asia-Pacific and rest of the world (RoW). Asia-Pacific (mainly due to China) is expected to grow at the highest CAGR during the forecast period. Whilst the biochemical methods are currently the largest (both volume and value), these are set to be overtaken by viral (mainly lentiviral and AAV) and physical (principally electroporation) methods as use switches from biomedical research to therapeutic delivery (Exhibit 14).

Exhibit 14: Competitors in the transfection market

Transfection technology	Companies	Devices/Products	Notes
Flow electroporation	MaxCyte	STX, VLX, GT	10^5-10^8 cells per minute
Static electroporation	BioRad	Gene Pulse, MicroPulser	10^5-10^7 cells per reaction
	BTX (Division of Harvard Apparatus)	ECM, Gemini, AgilePulse	10^4-10^8 cells per reaction
	Lonza	NucleoFector	10^4-10^7 cells per reaction
	Thermo Fisher Scientific	Neon	10^4-10^6 cells per reaction
Viral transfection	Lentigen	Lentivirus	GMP facility
	Oxford BioMedica	Lentivirus	GMP facility
	Takara Clontech, BioRad	Various	Kits for viral transfection
Biochemical transfection	Promega, Thermo Fisher Scientific, BioRad	Various methods including lipids, calcium phosphate, cationic polymers and DEAE-dextrin	Products are relatively cheap and used mainly by academic scientists
Biolistic particle delivery	BioRad	Helios Gene Gun	Simple, versatile technique, but with low efficiency

Source: Company websites

Well protected by patents, know-how, and trade secrets

To protect its commercial position, MaxCyte has patents covering the technology platform, the individual critical components and specific applications. Additionally it possesses substantial know-how and trade secrets relating to the development and commercialization of cell-therapy products. As one of the pioneers in the field, MaxCyte has a broad patent estate, with a multi-layered portfolio covered by 38 issued or pending patents in key jurisdictions.

The FDA Master File for MaxCyte's instruments provides the company with an additional competitive advantage as regulatory filings are simplified for its customers. The document includes information not disclosed in patents, but it is confidential, and MaxCyte's clients only need to reference it when making regulatory applications, without having precise knowledge of its contents. In fact, the presence of the FDA Master File should help to secure MaxCyte's position as a preferred partner for companies developing cell therapies. The reference to MaxCyte's Master File in a partner's regulatory filing serves to further tie the user to the use of MaxCyte's technology.

Sensitivities

Limited exposure to clinical trial risks

Although MaxCyte is exposed to many of the risks associated with investing in small- to mid-cap biotech companies, its risk profile is considerably lower than most such companies. This is because it has a fast-growing revenue stream, and the number of cell therapy alliances (that is likely to grow further due to the growth of the cell therapy field), which limits the exposure to the clinical readout from any one programme. That said, the quality of the clinical data from the ongoing and planned clinical trials with CARMA will be crucial in determining the likelihood and value of any potential licensing deals for CARMA.

CAR-T space is very competitive and dynamic and CARMA may struggle

Potential interest in CARMA from possible partners will also depend on advances from other companies developing CAR-T therapies; this area of science is very competitive. For instance, Bellicum Pharmaceuticals is developing CAR-T products with its CIDeCAR technology so that it can eliminate the infused CAR-T cells if toxicity is too high. Groups at University of Pennsylvania and University of Texas MD Anderson Cancer Center are addressing the issue of on-target/off-tumour toxicities by developing low affinity CAR-T therapies. Ziopharm is developing viral-free CAR-T and TCR cell therapies using Sleeping Beauty technology, licensed from MD Anderson, which allows treatment in less than two days. Finally, the October 2018 NASDAQ IPO of Allogene Therapeutics has provided significant funding for the potentially biggest threat to the CARMA platform with its allogeneic CAR-T cells. Other companies working on off-the-shelf CAR-T products include Juno/Celgene, and Gilead/Sangamo. Each of these companies highlights the opportunity for successful CAR therapies, and also the competition in the field.

Major companies focused on eroding MaxCyte's position in electroporation

The drug discovery and cell therapy revenue lines are growing due to the leading position MaxCyte enjoys in the field of flow electroporation. There are significant barriers to competitors, given its patent portfolio and trade secrets; however well-resourced companies such as BTX, Lonza and Thermo Fisher Scientific will be striving to break MaxCyte's dominance.

MaxCyte, like most biotech companies, is still dependent on the capital markets, and as with all equity raises, there is uncertainty regarding the pricing and size of any issuance. MaxCyte's ability to attract new investment into the company will determine the degree of dilution that current investors might face, and the rate at which it is able to execute its strategic plans.

We note that from November 28, MaxCyte's Regulation S restricted stock (MXCR.L) has consolidated into its Common Stock line (MXCT.L). The total number of shares will remain the same and all shares will trade under the MXCT.L ticker, with the MXCR.L ticker being cancelled. The intention is to improve liquidity and transparency for shareholders as prior to this date, restricted stock accounted for c 30% of outstanding shares.

Valuation

Valuation using a sum-of-the-parts DCF model suggests a value of £177m, or 347p per share

MaxCyte is not a typical drug discovery company; its technology platform is generating solid, and sustainable, revenues as it sells and licenses its electroporation systems for both early discovery (typically to research and academic units) and clinical (mainly to biotech and large pharma) applications. These recurrent revenue streams underpin the value of the company, with the potential significant upside from the proprietary CARMA pipeline.

The hybrid structure means that a classic rNPV model of the clinical portfolio would fail to capture the inherent value of the growing revenue streams; hence we have used a sum-of-the-parts that includes DCF calculated values for the two operating units and an equivalent estimate for the lumpier commercial licenses. All MaxCyte units are well positioned to continue to benefit from the interest in altering cells to treat currently intractable diseases, with its technology having the potential to be effectively embedded within a number of such treatments, not just CARMA-based therapies. Assuming clinical progress continues as expected, we envisage the proprietary CARMA pipeline will, over time, become a significant larger component of the valuation.

Exhibit 15: Sum-of-the-parts valuation model of MaxCyte

Cashflow	Notes	NPV ($m)	NPV (£m)	NPV/share (p)
Drug discovery & manufacturing	Three phase DCF: Sales growing at CAGR of 12.9% from $8.7m in FY17E to $18.0m in FY23E, before trending to 2% growth. Pre-G&A margin[1] growing from 30% to 45% in FY30E. Terminal growth rate is 2%.	61.9	47.6	92.8
Cell therapy	Three phase DCF: Sales growing at CAGR of 24.4% from $5.3m in FY17E to $19.6m in FY23E, before trending to 2% growth. Pre-G&A margin[1] growing from 5% to 55% in FY30E. Terminal growth rate is 2%.	91.2	70.1	136.7
Commercial license programmes	Five programmes each with an NPV of $10m, with first significant payment received in 2017 and each of the subsequent four years.	34.2	26.3	51.2
CARMA technology	Twice the value of MCY-M11 in ovarian cancer (Peak sales: $1.26bn, launch year: 2024, likelihood of success: 15%, royalty rate 18%, and developmental milestones totaling $150m), to take into account broader potential of CARMA platform.	103.5	79.6	155.2
G&A, CAPEX, dep & amort, changes in WCR	Three phase DCF: G&A increasing at a CAGR of 12.1% from $5.3m (31% of sales) in FY18E to $7.1m in FY23E trending to 18% of sales in FY30E.	(72.7)	(55.9)	(109.0)
Net cash	At H118	13.7	10.5	20.6
Total		**229.5**	**176.5**	**347.4**

Discount rate	10% for Drug discovery & manufacturing and Cell therapy businesses; 12.5% for CARMA project
Tax rate	20% from 2023
Exchange rate	$1.30/£1

Source: Trinity Delta; Note [1] For the purposes of the valuation, we have assumed that 50% of R&D excluding CARMA and sales & marketing expenses are allocated to Drug discovery and the remaining 50% to Cell therapy.

The highly-publicised progress seen in recent years means cell-based therapies have been materially de-risked, with a mounting body of clinical evidence raising investor confidence (and supporting the valuations of numerous companies) that such therapies will achieve significant commercial success.

We maintain conservative assumptions throughout

Exhibit 15 shows how our revised sum-of-the-parts model yields a valuation of £177m, or 347p per share. We previously valued the company at £166m or 327p per share. We have updated our methodology for the valuation of the CARMA platform to base it on the value of MCY-M11, rather than on the milestones from five potential deals, now that there is better clarity on the development pathway. We have also adopted conservative assumptions in our modelling; for instance, we have only included commercial licensing agreements for five programmes, which could be worth c$10m each, although there are now over 25 programmes with licenses covering clinical development and there are already such licensing agreements signed with CRISPR Therapeutics for four significant programmes. We feel this is currently appropriate but as progress is achieved, we would expect to revisit the model and anticipate the valuation would reflect this.

The model suggests that the current market cap of £99m materially undervalues the businesses and is supported solely by the revenue generating operations, with the potential of the CARMA platform being essentially in for free. This contrasts with the many companies that are developing CAR-T therapies which are worth well over $100m (Exhibit 16).

Exhibit 16: Market cap and enterprise values of selected companies developing CAR therapies

Company	Market cap ($m)	Enterprise value ($m)	Notes
Allogene	3,699	3,346	1 CAR-T therapy in Phase I and 16 preclinical programmes. Developing allogeneic CAR-T therapies.
Autolus	1,656	1,506	4 CAR therapies in Phase I/II clinical trials. Developing a range of next generation CAR-T, CAR and TCR cell therapies.
Atara Biotherapeutics	1,846	1,420	6 CAR-T therapies in preclincal development. Focused on T-cell immunotherapies, also has 4 other therapies in the clinic including tab-cel in Phase III for EBV infections.
Bellicum	197	58	1 CAR-T in solid tumours and 1 TCR therapy in Phase I/II trials. Therapies include CIDeCAR suicide switch. Therapy for HSCT in pivotal study.
Bluebird bio	6,051	4,755	CAR-T therapies in Phase II/III and Phase I/II studies. Three gene therapy products in clinical development including 2 in Phase II/III.
Celyad	297	231	1 CAR-T therapy in Phase I studies in haematological and solid tumours; allogeneic CAR-T therapy soon to enter the clinic in solid tumours.
Mustang Bio	94	46	4 CAR-T therapies in Phase I/II studies, in both haematalogical and solid tumours. Also a gene therapy in Phase I/II development for XSCID.
Ziopharm	445	396	2 CAR-T therapies in Phase I/ and IL-12 product soon to enter a pivotal study.

Source: Trinity Delta, Company data; Note: Market caps of companies at close on 4 December 2018.

Financials

Solid growth over past five years is expected to be sustained

MaxCyte's revenues have increased at a CAGR of 28.9% over the last five years, and are forecast to be $17.0m at FY18 (c 21.9% growth). We expect such growth rates will accelerate because of the increasing use of modified cell lines in drug discovery and progress of cell therapies, greater investment in sales and marketing, and the recent extension to the clinical and commercial agreement with CRISPR Therapeutics into the field of oncology. Our sales forecasts are shown in Exhibit 14; we estimate that c60% of revenues are derived from drug discovery and manufacturing sales and c40% from cell therapy. There is upside to these estimates from additional potential licensing agreements covering the commercial use of MaxCyte's devices, such deals tend to result in early payments of c$1m, with clinical milestones and eventual sales milestones and/or royalties on sales, on top of the revenues from the leasing of instruments and disposables.

A summary of the changes to our previous estimates are shown in Exhibit 17. The main amendment to our model is the reduction in CARMA-related R&D expenses in FY18, due to the time taken for the FDA to give IND clearance for the first clinical trial with this novel cell therapy. We have also adjusted the balance of the other expenses following MaxCyte's H118 results.

Exhibit 17: Summary of changes to estimates

	Sales ($m)			EBITDA ($m)			Adj. EPS ($)		
	Old	New	Change	Old	New	Change	Old	New	Change
2018E	17.0	17.0	0.0%	(13.0)	(10.4)	N/A	(27.3)	(22.2)	N/A
2019E	20.3	20.5	0.1%	(12.7)	(13.5)	N/A	(27.2)	(28.4)	N/A

Source: Trinity Delta

Increased investment in the proprietary pipeline

Management is delivering on its promise to exploit its technology in developing a pipeline of proprietary programmes. The start of the Phase I study with MCY-M11 marks the first patient treatment with the CARMA platform and should, if successful, lead to the progression of other promising candidates into the clinic. MCY-M11 might be out-licensed to a larger player to conduct the more expensive pivotal clinical trials on the back of the data from the Phase I study; however, additional trials might be required to maximise the value of the asset.

The company is currently well financed, with $18.8m of cash and equivalents at H118, which we forecast will allow the company to operate into FY20. We estimate that in order to execute its clinical development plans in a rigorous and timely manner, while also sustaining its investment in its service operations, MaxCyte will need an additional £25m to £30m of funds. This could be achieved through issuing debt or equity, or from significant licensing fees. Although we freely admit that our assumptions are based on little more than intuition and experience, we believe that a fundraising of this order would provide management the resources to progress its plans effectively.

Exhibit 18: Summary of financials

Year-end: December 31	$m	2015	2016	2017	2018E	2019E	2020E
INCOME STATEMENT							
Revenues		**9.3**	**12.3**	**14.0**	**17.0**	**20.5**	**24.4**
Cost of goods sold		(1.0)	(1.3)	(1.5)	(2.0)	(2.5)	(2.9)
Gross Profit		**8.3**	**11.0**	**12.5**	**15.1**	**18.0**	**21.5**
R&D expenses (excluding CARMA)		(2.7)	(3.4)	(3.8)	(5.5)	(6.6)	(7.8)
R&D expenses (CARMA)		(0.3)	(1.3)	(7.5)	(8.0)	(11.4)	(12.0)
Sales and marketing expenses		(3.3)	(4.8)	(6.0)	(7.0)	(8.2)	(10.0)
General and administrative expenses		(2.7)	(4.2)	(4.5)	(5.3)	(5.7)	(6.0)
Underlying operating profit		**(0.8)**	**(2.7)**	**(9.3)**	**(10.8)**	**(13.9)**	**(14.4)**
Underlying operating profit (excluding CARMA)		**(0.5)**	**(1.4)**	**(1.8)**	**(2.7)**	**(2.4)**	**(2.3)**
Other revenue/expenses		0.0	0.0	0.0	0.0	0.0	0.0
EBITDA		**(0.7)**	**(2.6)**	**(9.1)**	**(10.4)**	**(13.5)**	**(13.9)**
EBITDA (excluding CARMA & share-based payments)		**(0.4)**	**(1.2)**	**(1.1)**	**(1.4)**	**(1.0)**	**(0.7)**
Operating Profit		**(0.8)**	**(2.7)**	**(9.3)**	**(10.8)**	**(13.9)**	**(14.4)**
Interest expense		(0.7)	(0.6)	(0.6)	(0.6)	(0.6)	(0.6)
Profit Before Taxes		**(1.4)**	**(3.3)**	**(9.9)**	**(11.4)**	**(14.5)**	**(15.0)**
Adj. PBT		**(1.4)**	**(3.3)**	**(9.9)**	**(11.4)**	**(14.5)**	**(15.0)**
Current tax income		0.0	0.0	0.0	0.0	0.0	0.0
Cumulative preferred stock dividend		(2.1)	(0.5)	0.0	0.0	0.0	0.0
Net Income		**(3.5)**	**(3.9)**	**(9.9)**	**(11.4)**	**(14.5)**	**(15.0)**
EPS (c)		**(186.4)**	**(11.5)**	**(20.4)**	**(22.2)**	**(28.2)**	**(29.2)**
Adj. EPS (c)		**(186.4)**	**(10.0)**	**(20.4)**	**(22.2)**	**(28.2)**	**(29.2)**
DPS (c)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		1.9	33.5	48.6	51.1	51.3	51.3
Gross margin		*89%*	*89%*	*90%*	*88%*	*88%*	*88%*
BALANCE SHEET							
Current assets		**6.2**	**15.8**	**30.6**	**20.6**	**8.5**	**11.2**
Cash and cash equivalents		2.4	11.7	25.3	13.8	0.6	1.9
Accounts receivable		1.5	2.4	3.2	3.7	4.5	5.4
Inventories		1.1	1.3	1.3	1.9	2.4	2.8
Other current assets		1.2	0.3	0.7	1.1	1.1	1.1
Non-current assets		**0.2**	**0.3**	**0.8**	**1.3**	**1.6**	**1.9**
Property, plant & equipment		0.2	0.3	0.8	1.3	1.6	1.9
Other non-current assets		0.0	0.0	0.0	0.0	0.0	0.0
Current liabilities		**(5.1)**	**(5.7)**	**(7.2)**	**(6.9)**	**(8.6)**	**(25.5)**
Short-term debt		(0.8)	(0.0)	(0.9)	0.0	0.0	(15.0)
Accounts payable		(2.3)	(3.2)	(4.3)	(4.4)	(5.5)	(6.6)
Other current liabilities		(2.0)	(2.5)	(2.1)	(2.5)	(3.1)	(3.9)
Non-current liabilities		**(4.4)**	**(5.3)**	**(4.6)**	**(5.6)**	**(5.6)**	**(5.6)**
Long-term debt		(4.2)	(5.0)	(4.2)	(5.0)	(5.0)	(5.0)
Other non-current liabilities		(0.2)	(0.3)	(0.4)	(0.5)	(0.5)	(0.5)
Equity		**(3.1)**	**5.1**	**19.6**	**9.4**	**(4.1)**	**(17.9)**
Share capital		45.3	56.8	81.2	81.8	81.8	81.8
Other		(48.4)	(51.7)	(61.6)	(72.4)	(85.8)	(99.7)
CASH FLOW STATEMENTS							
Operating cash flow		**(0.2)**	**(2.3)**	**(9.7)**	**(11.0)**	**(12.6)**	**(12.9)**
Profit before tax		(1.4)	(3.3)	(9.9)	(11.4)	(14.5)	(15.0)
Non-cash adjustments		0.2	0.3	0.8	1.6	2.1	2.2
Change in working capital		1.1	0.7	(0.5)	(1.0)	0.5	0.5
Interest paid		0.0	0.0	0.0	(0.3)	(0.6)	(0.6)
Taxes paid		0.0	0.0	0.0	0.0	0.0	0.0
Investing cash flow		**(0.1)**	**(0.2)**	**(0.6)**	**(0.7)**	**(0.7)**	**(0.8)**
CAPEX on tangible assets		(0.1)	(0.2)	(0.6)	(0.7)	(0.7)	(0.8)
Other investing cash flows		0.0	0.0	0.0	0.0	0.0	0.0
Financing cash flow		**(0.7)**	**11.9**	**23.9**	**0.2**	**0.0**	**15.0**
Proceeds from equity		0.0	11.9	23.9	0.2	0.0	0.0
Increase in loans		(0.1)	(0.1)	(0.0)	(0.0)	0.0	15.0
Other financing cash flow		(0.7)	0.0	0.0	0.0	0.0	0.0
Net increase in cash		**(1.0)**	**9.3**	**13.6**	**(11.5)**	**(13.3)**	**1.3**
Cash at start of year		3.4	2.4	11.7	25.3	13.8	0.6
Cash at end of year		**2.4**	**11.7**	**25.3**	**13.8**	**0.6**	**1.9**
Net cash at end of year		**(2.6)**	**6.7**	**20.3**	**8.8**	**(4.5)**	**(18.1)**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. No new commercial licensing deals are included in our forecasts. The short-term debt in FY20 is indicative of the company's funding requirements

Company information

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Top institutional shareholdings

	% holding
Intersouth Partners VI	15.69
River and Mercantile Asset Management	11.35
Bost-Jackson	7.44
Harbert Venture Partners	7.25
Legal & General Investment Management	6.87
Unicorn AIM VCT	5.39
Wendell M Starke	3.69
MASA Life Science Ventures	3.64
Total disclosable holdings	**61.32**
Other shareholders	38.68
Total shareholders	**100.00**

Source: MaxCyte

Key personnel

Person	Position	Biography
Dr Stark Thompson	Non-Executive Chairman	Former President & CEO of Life Technologies Inc (now Thermo Fisher). Also formerly Director of Luminex (Nasdaq LMNX), Chairman of GeneLogic (Nasdaq GLGC), and active with several educational and non-profit organisations. Holds a Bachelor degree in Chemistry from Muskingum College and a PhD in Physiological Chemistry from Ohio State University.
Douglas A Doerfler	President and CEO	Founded MaxCyte in July 1998. Previously President, CEO and a Director of Immunicon Corporation, a private cell-based therapy and diagnostics company. Prior to this, had a number of executive positions with Life Technologies Inc (now Thermo Fisher). Holds a Bachelor degree in Finance from the University of Baltimore School of Business and a Certificate in Industrial Relations.
Ronald Holtz	CFO	CFO since 2005. Previously CFO at B2eMarkets, a private software company, and RWD Technologies Inc, a public information technology and consulting firm. Prior to this experience with Ernst & Young. Has a Bachelor's degree in mathematics from the University of Wisconsin, an MBA from the University of Maryland and is a CPA.
Dr Claudio Dansky Ullman	CMO	CMO since 2018, with responsibility for clinical development of the CARMA drug development programme. Previously senior VP and head of clinical development at Infinity Pharmaceuticals, a public oncology-focused biopharmaceutical company. Prior roles included senior medical director and global clinical lead for the Oncology Therapy Area Unit at Takeda Pharmaceuticals, and as senior investigator in numerous early-phase and late-phase clinical trials as part of the Cancer Therapy Evaluation Program of the National Cancer Institute (NCI). Also held research roles at the National Institute of Health and postdoctoral fellowship positions in tumour immunotherapy and drug resistance at the NCI. Has an MD from the School of Medicine, University of Buenos Aires, and completed medical oncology training at Guemes Private Hospital, Buenos Aires.

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