Trinity Delta

MaxCyte

Update

Strategic investments to support partners & future growth

6 September 2022

MaxCyte's H122 total revenue of $21.2m grew 56% year-on-year, with core Cell Therapy and Drug Discovery revenues up 46.5% to $19.2m, prompting management to increase FY22 guidance to c 30% core business revenue growth. Guidance for the inherently lumpier programme-related revenues from Strategic Platform Licences (SPLs) remains at c $4m for FY22. First regulatory filings for the most advanced SPL asset, CRISPR Therapeutics' exa-cel (CTX001) should occur in Q422, meaning a first approval decision could come as early as 2023. With the prospect of future commercial launches, a growing number of SPL partners (now 17) and clinical progress across the SPL stable, MaxCyte is investing in people, processes, products, and infrastructure to support this, to further consolidate its leading position in non-viral cell delivery and engineering, and to expand into new markets. Our updated valuation is £980m ($1.27bn) or 964p/$12.53 per share.

Year-end: December 31	2020	2021	2022E	2023E
Revenues (US$m)	26.2	33.9	44.9	57.7
Adj. PBT (US$m)	(11.8)	(19.1)	(34.8)	(36.7)
Net Income (US$m)	(11.8)	(19.1)	(34.8)	(36.7)
EPS (USc)	(17.0)	(21.4)	(34.4)	(36.0)
Cash (US$m)	34.8	255.0	222.1	188.7
Adj. EBITDA (US$m)	(7.5)	(8.8)	(24.5)	(25.2)

Source: Trinity Delta Note: Adjusted numbers exclude exceptionals and share based compensation.

- **Solid growth with further opportunities** Raised core business guidance is ahead of MaxCyte's c 23% five-year revenue CAGR (2017-21). Recurring revenues (from instrument sales and leases, disposables sales) from Cell Therapy and Drug Discovery customers provide good visibility and support c 90% pharma-like gross margins. SPL partners are now driving much of the core business top line; they also represent significant (>$1.25bn) pre-commercialisation milestone potential. With a larger number of underlying SPL assets progressing through the clinic, programme-related revenue from such milestones should start to smooth, and the prospect of future commercial revenues (sales milestones, royalties or equivalent) should transform MaxCyte's mid- and longer-term revenue profile from 2024+.
- **Preparing for launch** MaxCyte's end-June 2022 cash of $240.9m provides ample funds to support investment into several key initiatives which align its capabilities and products with existing client needs (eg scale up for commercialisation) and in expansion into potential new applications and markets (as diverse as large scale bioprocessing with the VLx; new opportunities in gene editing novel cell types; and serving new geographies eg a first Asia-Pac SPL with LG Chem). Investments include infrastructure (a new HQ with in-house manufacturing), application and process development, and people (sales and marketing, field, regulatory support).
- **£980m / $1.27bn valuation (964p / $12.53 per share)** Updating our model following Q222 results, updates from SPL partners, and latest guidance generates a new valuation of £980m ($1.27bn) or 964p /$12.53 per share, vs £1.06bn ($1.39bn), or 1,050p / $13.64 per share, previously.

Price (UK share)	440.0p
(US common share)	$5.06
Market Cap	£447.6m $513.8m
Enterprise Value	£262.3m $272.9m
Shares in issue (shares)	101.7m
12 month range	280p-1,235p $3.36-$17.26
Free float	86.2%
Primary exchange	AIM
Other exchanges	NASDAQ
Sector	Healthcare
Company Code	MXCT.L MXCT
Corporate client	Yes

Company description

MaxCyte's partners use its patented flow electroporation platform to transfect a wide array of cells. Revenues arise from sale and lease of equipment, disposables and licence fees from an impressive client list. Key programmes with several clients are gaining greater visibility and approaching material value-inflection points. These will trigger a stream of milestone fees.

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MaxCyte: delivery on financial and strategic aims

MaxCyte remains well-positioned within the cell engineering field and has ample funds (end-Q222 cash of $240.9m) to support and expand the adoption of its enabling technologies and expertise in cellular based research, development, and commercialisation. Robust demand from Cell Therapy customers underpins increased FY22 guidance for the core business of c 30% revenue growth, ahead of MaxCyte's c 23% five-year revenue CAGR (2017-21). Despite a challenging macro environment, investment into engineered cell therapies and in new company creation remains resilient, with MaxCyte in a good place to capitalise on this. 2022 is a key year for strategic investments in people, processes, and products which should augment the company's ability to both support existing partners as they progress through the clinic and ultimately towards commercialisation, and to facilitate expansion into new markets. In our view MaxCyte is a unique and diversified play on the whole cell engineering field, providing broad exposure across cell types, technologies, indications, and approaches. Our valuation is £980m / $1.27bn (964p or $12.53 per share).

Multiple growth drivers with investment in place to exploit further opportunities

2022 is an important year for MaxCyte as the company positions itself to exploit future growth opportunities, both in supporting its partners as they approach potential commercial launches and in expanding its capabilities to address new markets (ie new applications such as bioprocessing or new geographies). Strategic investments across the company with the aim of driving revenue growth include increasing headcount to bolster the scientific, sales and marketing, regulatory, and field application support teams. A move to new headquarters is a major initiative that will provide faster and more scalable in-house manufacturing and more robust infrastructure as customers transition from research to commercial scale in preparation for pivotal studies and potential launches. Current resources of $240.9m (FY22e cash of c $220m), coupled with modest cash burn and growing revenues provides ample funds for ongoing and planned investments.

Wide applicability and proven expertise cements position in growing clinical applications

The ExPERT platform, used to enable a broad range of cell types and approaches across a wide range of indications, is seeing increasing industry adoption within growing target markets. MaxCyte's customer base spans from academic to translational science through to small innovative biotech companies and more established pharma/biotech players. Strength in the core business (Cell Therapy and Drug Discovery) is largely driven by recurring revenues from instrument leases and disposables sales. The move into later-stage clinical development by customers should increase instrument placement and processing assembly usage. The expectation of continued growth over the coming years reflects the high level of visibility in these recurring revenues and the strong underlying demand for MaxCyte's enabling technologies by customers.

The growing SPLs provide material longer-term upside

An increasingly important customer segment are Strategic Platform Licence (SPL) partners. MaxCyte's 17 current SPLs represent >$1.25bn in potential pre-commercialisation milestones and, contingent on success, offer the prospect of meaningful albeit undisclosed downstream economics (sales milestones, royalties or equivalent). Our March 2022 Outlook and April 2022 Update notes explore SPLs, progress of underlying assets, and the building of a milestone stack which should help transform MaxCyte's mid- and longer-term revenue profile.

Strategic Platform Licences: a recap on progress

Number of SPLs has reached critical point, providing internal hedges and material upsides

MaxCyte has secured 17 SPL partners to date, which cover >95 programmes with over 15% currently in the clinic. We summarise recent (Exhibit 1) and upcoming (Exhibit 2) news flow at SPL partners for assets we believe are under an SPL.

Exhibit 1: Recent news flow at disclosed clinical/commercial licence partners

Partner	Recent pipeline newsflow
Allogene Therapeutics (NASDAQ: ALLO)	**ALLO-715**: FDA ODD (Aug 2021) & RMAT designation (April 2021); initial Phase I UNIVERSAL r/r MM data at ASH 2020 with further Phase I UNIVERSAL data at ASH 2021 **ALLO-715 + nirogacestat**: combination cohort initiated in Phase I UNIVERSAL trial (April 2021), decision not to advance combination into dose expansion cohorts (Aug 2021) **ALLO-501** and **ALLO-501A**: interim Phase I ALPHA & ALPHA2 r/r NHL data at ASCO 2021 & ASH 2021; FDA RMAT Designation for ALLO-501A in r/r LBCL (June 2022) **ALLO-316**: FDA Fast Track Designation in RCC (March 2022) **ALLO-605**: FDA Fast Track Designation (June 2021); initiation of dose escalation in Phase I IGNITE study in r/r MM (June 2021); FDA Orphan Drug Designation for r/r MM (May 2022)
Beam Therapeutics (NASDAQ: BEAM)	**BEAM-201**: IND filing in r/r T-cell ALL (June 2022); FDA clinical hold (July 2022)
Caribou Biosciences (NASDAQ: CRBU)	**CB-010***: initial data from Phase I ANTLER trial in r/r B-cell NHL at EHA 2022
Celularity (NASDAQ: CELU)	**CYNK-001**: protocol amendment in Phase I AML trial (Dec 2021); business decision to terminate recruitment in Phase I GBM study of IV vs IT admin (Jan 2022) **CYNK-101**: FDA Fast Track designation (Jan 2022) and ODD (Feb 2022) in first-line HER+ gastric/GEJ cancer; dosing of first patient in Phase I/IIa gastric/GEJ cancer study (July 2022) **CyCART-19**: IND filing in B-cell malignancies (Q122); FDA additional info request (May 2022)
CRISPR Therapeutics (NASDAQ: CRSP)	**CTX001 (exa-cel)***: data from pivotal Phase I/II/III CLIMB-111 TDT & CLIMB-121 SCD studies at EHA 2022 & EHA 2021; EMA PRIME designation in TDT (April 2021); enrolment complete in CLIMB-111 & CLIMB-121 (Q321); completion of regulatory discussions with EMA & UK MHRA (Q222); initiation of paediatric CLIMB-131 TDT & CLIMB-141 SCD Phase III trials (Q222) **CTX110**: Phase I CARBON data in r/r NHL (Oct 2021); FDA RMAT designation (Nov 2021); expansion of CARBON into pivotal trial with consolidation dosing (Q122) **CTX120**: top line Phase I data in r/r MM (H122); decision to pivot to next-gen allogeneic CAR-T programme for MM (CTX121) with aim to improve efficacy and competitive profile (June 2022) **CTX130**: initial data from Phase I COBALT-LYM trial in T & B cell malignancies at EHA 2022, initial data from Phase I COBALT-RCC trial in RCC (June 2022)
Editas Medicine (NASDAQ: EDIT)	**EDIT-301***: initiation of dosing in Phase I/IIa RUBY SCD trial (H122); lift of RUBY FDA partial hold (July 2022); FDA Rare Pediatric Disease Designation (April 2022) & FDA ODD in TDT (May 2022)
Myeloid Therapeutics	**MT-101**: start of Phase I/II IMAGINE trial in PTCL (Dec 2021); first patient dosed (May 2022)
Precision BioSciences (NASDAQ: DTIL)	**PBCAR0191 (azer-cel)*:** interim Phase I/IIa r/r NHL & r/r B-ALL data at ASH 2021 & in June 2022 **PBCAR19B**: Phase I start in NHL (July 2021); manufacturing optimization process complete (Q222) **PBCAR269A***: initial data from Phase I/IIa in r/r MM at ASH 2021; DL3 start of nirogacestat combination cohort (mid-2022)
Vor Biopharma (NASDAQ: VOR)	**VOR33***: FDA Fast Track Designation in AML (Sept 2021); initiation of Phase I/IIa VBP101 trial in AML (Aug 2021)

Source: Trinity Delta, Company websites; Clinicaltrials.gov Note: * = confirmed as MaxCyte-enabled programmes, for Allogene specific allogeneic CAR-T programmes have not been explicitly identified; ALL = acute lymphoblastic leukaemia; AML = acute myeloid leukaemia; B-ALL = B-cell ALL; DL3 = dose level three; GEJ = gastroesophageal junction; IV = intravenous; IT = intratumoral; LBCL = large B cell lymphoma; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; ODD = orphan drug designation; PTCL = peripheral T cell lymphoma; RCC = renal cell carcinoma; RMAT = regenerative medicine advanced therapy; r/r = relapsed/refractory; SCD = sickle cell disease; TDT = transfusion-dependent ß-thalassaemia

Exhibit 2: Upcoming news flow at disclosed clinical/commercial licence partners

Partner	Upcoming pipeline newsflow
Allogene Therapeutics (NASDAQ: ALLO)	**ALLO-501A**: initiation of potentially pivotal Phase II ALPHA2 trial in r/r LBCL (mid-2022); longer-term follow-up data from Phase I portion of ALPHA & ALPHA2 (late-2022) **ALLO-316**: initial data from Phase I TRAVERSE RCC trial (2022); initiate studies in potential second solid tumour indication (2022) **ALLO-715**: longer-term follow-up data for monotherapy from Phase I UNIVERSAL r/r MM study (late-2022); full BCMA programme clinical update, including potential Phase II study approach & timing (by end-2022) **ALLO-605**: full BCMA programme clinical update, including potential Phase II study approach & timing (by end-2022)
Beam Therapeutics (NASDAQ: BEAM)	**BEAM-101**: initiation of enrollment in Phase I/II BEACON-101 trial in SCD (H222) **BEAM-102**: IND filing in SCD (H222) **BEAM-201**: lift of FDA clinical hold (TBD) **Other**: nomination of second CAR-T development candidate (2023)
Caribou Biosciences (NASDAQ: CRBU)	**CB-010***: further cohort 1 Phase I ANTLER data (by end 2022) **CB-011**: IND filing in r/r MM (Q422) **CB-012**: IND filing in r/r AML (2023)
Celularity (NASDAQ: CELU)	**CYNK-001**: initial data from Phase I AML trial (H222); estimated AML trial completion (2023) **CYNK-101**: IND filing for CYNK-101 in combination with monoclonal antibodies (TBC) **CyCART-19**: start Phase I/II in B-cell malignancies pending resolution of FDA questions (2023)
CRISPR Therapeutics (NASDAQ: CRSP)	**CTX001 (exa-cel)***: regulatory submissions in TDT and SCD with EMA and UK MHRA (Q422); completion of regulatory discussions with FDA (H222) **CTX110**: additional data from CARBON trial (H222) **CTX112**: IND filing for next-generation anti-CD19 construct (by end 2022) **CTX120**: Phase I r/r MM data presentation at future conference (2022) **CTX131:** IND filing for next-generation anti-CD70 construct (by end 2022)
Editas Medicine (NASDAQ: EDIT)	**EDIT-301***: initiation of dosing in Phase I/II EDITHAL trial in TDT (by end-2022); initial Phase I/IIa RUBY data in SCD (by end-2022)
Intima Bioscience	**Lead eTIL CISH knock out**: completion of Phase I/II gastrointestinal cancer study (H222)
invIOs	**APN401**: determine MTD (2022); first solid tumour efficacy data (2023); Phase II start (2024)
Kite Pharma (Gilead)	**KITE-037**: submit IND/initiate Phase I/II trial (TBC)
KSQ Therapeutics	**KSQ-001**: complete IND-enabling studies
Myeloid Therapeutics	**MT-201**: start Phase I DEMAND trial in GBM (Aug 2022)
Precision BioSciences (NASDAQ: DTIL)	**PBCAR0191***: next dose cohort of optimised PBCAR0191 in Phase I/IIa study in r/r B-ALL; request of FDA meeting to discuss data and path forward (H222); further update on progress (end-2022) **PBCAR19B**: resumption of dosing (DL2) with optimised cells in Phase I in NHL (Q322); programme update (end-2022) **PBCAR269A***: programme update in r/r MM (end-2022) **CD19 combination with foralumab**: IND amendment (2022)
Sana Biotechnology (NASDAQ: SANA)	**SC291**: IND filing (H222) **Multiple programmes (including SC276 and SC255)**: submit INDs (2023/24)
Vor Biopharma (NASDAQ: VOR)	**VOR33***: initial data on human engraftment / protection from Phase I/IIa VBP101 AML study (Q422); VOR33/VCAR33^{ALLO} combo IND filing (post-initial clinical data as monotherapies)

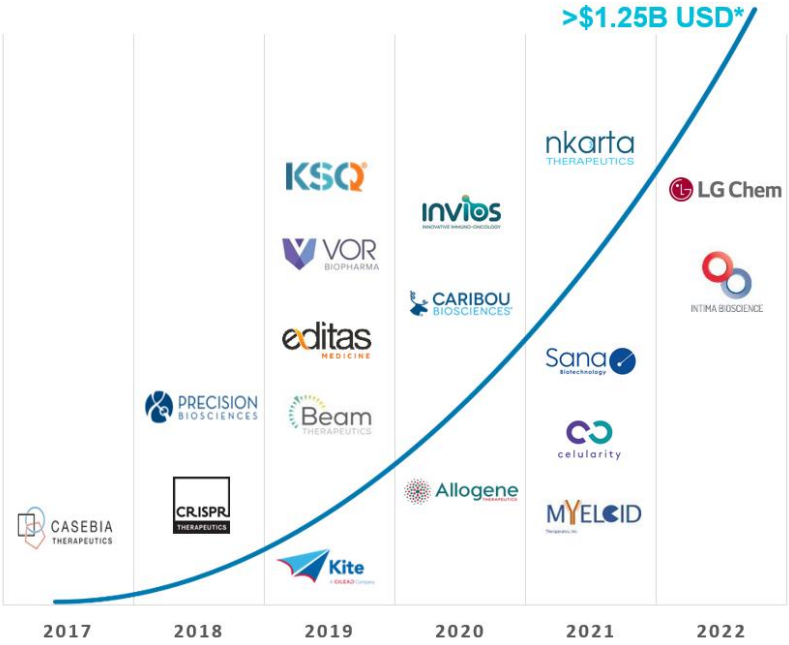
Source: Trinity Delta, Company websites; Clinicaltrials.gov Note: * = confirmed as MaxCyte-enabled programmes, note that for Allogene specific allogeneic CAR-T programmes have not been explicitly identified; ALL = acute lymphoblastic leukaemia; AML = acute myeloid leukaemia; B-ALL = B-cell ALL; BCMA = B-cell maturation antigen; DL2 = dose level two; GBM = glioblastoma multiforme; LBCL = large B cell lymphoma; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; RCC = renal cell carcinoma; r/r = relapsed/refractory; SCD = sickle cell disease; TDT = transfusion-dependent ß-thalassaemia

Broadening horizons and diversifying risk

Latest SPL with LG Chem is the first from Asia-Pacific region

MaxCyte has steadily been increasing the number of multi-asset SPLs signed since the first in 2017, adding two new SPLs so far in 2022: Intima Bioscience in February and LG Chem in July. The latter deal with a South Korea headquartered multinational company is notable as it is MaxCyte's first SPL in Asia, demonstrating execution on an objective to broaden geographic reach as stated at the time of the NASDAQ IPO. Under this SPL, MaxCyte's technologies will support development and commercialisation of LG Chem's solid tumour CAR-T programmes including preclinical stage lead next-generation candidate LR19023.

Exhibit 3: Number of SPLs continues to increase



Source: MaxCyte Note: * cumulative potential pre-commercialisation milestones as of Jan 2022

Number of potential future SPL targets continues to grow; aiming for three each year

According to management assessment there are currently over 50 potential SPL partners globally. This figure is derived from the number of preclinical stage gene-modified cell therapy companies active in immuno-oncology and inherited disorders that use non-viral *ex vivo* delivery. Over time, cell therapy pipeline growth, new entrants onto the market, and the ongoing industry shift towards non-viral delivery technologies due to new indications and novel approaches requiring more sophisticated or complex engineering could grow this further. This all bodes well for market expectations of three new SPLs secured each year, and management continues to confirm that the pipeline of SPL opportunities remains strong and diverse.

As development progress is achieved, the visibility and value of each SPL rises

An expanding breadth of SPLs and growth in cell therapy R&D and rising demand for MaxCyte's enabling technologies should increase the number of SPLs (and number of underlying assets with milestone potential). As the number of SPLs and underlying assets increase, the preclinical and clinical development progress of these assets will contribute to building a sizeable pre-commercial milestone stack. Over time as the number of discrete milestone trigger events become more frequent and a greater proportion of these events involve larger $ milestones (on clinical success and/or regulatory approval) there will be a smoothing of the current fluctuations seen in Programme-related revenues.

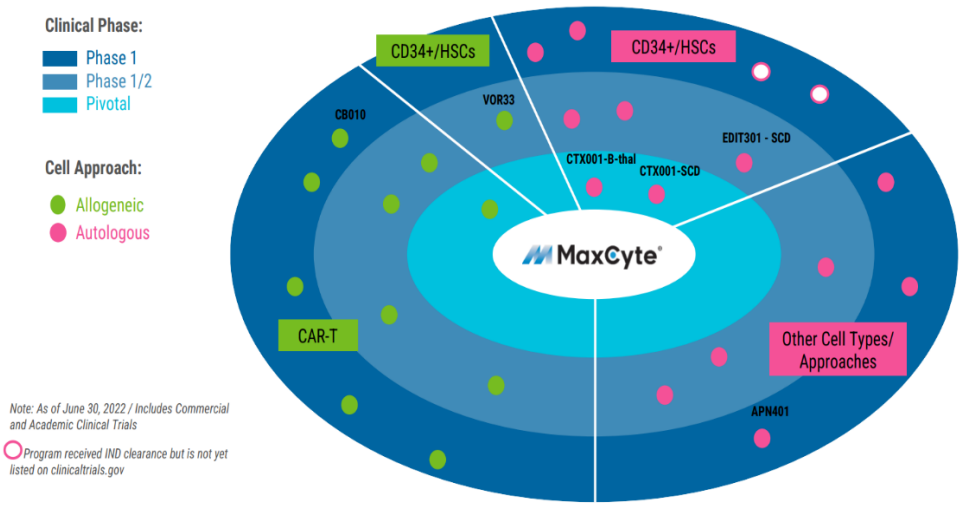
An interesting, and lower risk, play on the *ex vivo* cell therapy space

We highlight that as a key enabler for multiple diverse *ex vivo* cell therapies, MaxCyte retains much of the upside potential associated with the sector but with a considerably lower risk profile. Drug development carries inherent risks, including failure or delay in clinical development or the regulatory process, and the highly innovative nature of the cell therapies under development by partners means they carry a higher than typical risk. However, MaxCyte's exposure to any one programme or partner is limited by the number of SPL partners, the diversity of the underlying technologies, and the range of indications addressed. Given the highly innovative and complex nature of these engineered cell therapies and the nascent stage of the scientific field, we also expect there to be pipeline rationalisation based on clinical and commercial considerations, especially as several programmes may be addressing the same targets. Rationalisation should not always be considered a negative: the pioneering programmes affected could provide important validation and scientific knowledge, and early go/no go decisions mean that the partner company saves both time and money in subsequently developing a potentially more effective and competitively differentiated drug.

Early learnings provide opportunities for SPL partners to develop optimal candidates

This has recently been seen at two SPL partners: CRISPR Therapeutics and Beam Therapeutics. CRISPR Therapeutics, at its June 2022 Innovation Day, revealed revised expectations for its allogeneic CAR-T programmes. Proof of concept has been achieved with its lead programmes CTX110 (currently in a potentially registrational trial, with a pivotal arm added to the Phase I/II CARBON trial) and CTX130 (two Phase I/II trials ongoing: COBALT-LYM and COBALT-RCC). However, early-stage work on second-generation programmes with novel potency edits (that improve tumour killing and resistance to suppression) means it will now be filing INDs for two next-generation constructs (CTX131 and CTX112) by the end of 2022. In addition, CTX121, currently a research-stage next-generation asset, will replace multiple myeloma candidate CTX120 (discontinued based on assessment of competitive profile). Similarly, Beam Therapeutics has announced a delay to the nomination of its second CAR-T development candidate as additional multiplex editing work is needed to identify the number and type of base edits required to make cells fully allogeneic.

Exhibit 4: MaxCyte-enabled active clinical trials



Source: MaxCyte Note: includes commercial and academic clinical trials, hence not all relate to SPL partners/assets

Risk paradox: limited downside but material upside if even a fraction of the underlying assets succeed

At this stage in MaxCyte's development, there is also an asymmetry. Downside exposure to the fortunes of a single SPL programme or partner is limited by the growing size and diversity of its SPL portfolio (with some underlying assets shown in Exhibit 4) but, conversely, the success of a single programme could transform its revenue profile. The most advanced SPL programmes is CRISPR Therapeutics' CTX001 (exa-cel or exagamglogene autotemcel). First regulatory filings will be made in Q422, implying a potential approval decision in late-2023 and, if successful, launch(es) in 2024.

Preparing for first launch

CRISPR Therapeutics update was highly reassuring…

At its June 2022 Innovation Day, CRISPR Therapeutics indicated that it is on track to file an MAA (Marketing Authorisation Application) with the EMA and UK MHRA for exa-cel in sickle cell disease (SCD) and transfusion dependent β-thalassemia (TDT) in Q422. Discussions are ongoing with the FDA regarding the filings of a BLA (Biologics Licence Application), and are expected to be completed by year-end, when we would expect guidance on the US regulatory timings.

…with a landmark first product approval as early as late-2023

These first regulatory filings will be a landmark for MaxCyte. A first approval decision could come in late-2023 at the earliest; if positive, and pending payor/reimbursement discussion, the first launch of an SPL asset could occur in 2024. From a financial perspective, MaxCyte has previously indicated that milestones for BLA/MAA approval are typically mid-seven figures (potentially per major region), and commercial revenues could include sales royalties, disposables use, and/or other sales-based payments. In our modelling, we assume a 2% blended royalty to capture post-commercial revenues. We do not anticipate first post-commercialisation revenues to MaxCyte until 2024 at the earliest.

Such progress means we begin to look beyond the milestone values of each SPL

The value of an individual SPL asset to MaxCyte depends on several factors, not solely the likelihood of triggering milestone payments. Commercial revenue potential will depend on the size of the target indication and addressable market, COGS, pricing and reimbursement, and specifics of the enabling technology and service provided by MaxCyte. Consequently, we explore some of these influencing factors below.

Deal economics provide insights into commercial expectations

External indications of exa-cel programme value include the April 2021 amendment to the economics of the collaboration deal between CRISPR Therapeutics and Vertex Pharmaceuticals. The additional 10% of profit secured by Vertex in exchange for bearing an extra 10% of costs, plus a $900m upfront milestone and a further $200m payment on regulatory approval, implies a $10bn+ product valuation. More recently, the CRISPR Therapeutics CEO has commented that street expectations for exa-cel may be too low, as Vertex has drawn parallels with its triple-combination therapy Trikafta which has transformed the treatment of cystic fibrosis patients. Trikafta, FDA approved in October 2019 and as Kaftrio in August 2020 by the EMA, generated FY21 revenues of $5.70bn (+47% on FY20) and revenues of $3.66bn in H122.

Potentially functional cures bring new issues into focus…

Data presented at the 2022 European Haematology Association (EHA) meeting from the CLIMB-111 TDT and CLIMB-121 SCD trials indicates that exa-cel could potentially be a functional cure. CRISPR Therapeutics estimates that the current addressable market in the US and EU for exa-cel, using standard of care conditioning, is >30k patients (split 5k TDT and 25k SCD). Use of a targeted

conditioning regime could expand this addressable market to encompass a further 9k TDT patients and 125k SCD patients. Similarly, positive outcomes from the two recently initiated paediatric Phase III trials in TDT (CLIMB-131) and SCD (CLIMB-141) would support a potential filing in a younger age group (<12 yr olds).

...including likely uptake, pricing models, and revenue recognition

Gene therapies such as exa-cel are targeting severe disease, where a 'one and done' potentially curative therapy would be transformative, although questions remain about likely uptake. Uptake will be determined by safety and efficacy (in particular, lack of durability), and pricing/reimbursement, with the need for pre-conditioning limiting the addressable patient population to those with severe disease. We note that SCD is increasingly a disease area of interest given the unmet medical need. The $5.4bn acquisition of Global Blood Therapies by Pfizer announced in August 2022 was predicated on its SCD franchise, including Oxbryta (FY21 revenue: $195m) for mild to moderate SCD; however, we highlight that this is a different, less severely affected, market to that targeted by exa-cel.

An exciting time ahead with multiple players reaching key decision points

Exa-cel's competition will come from other companies that have *ex vivo* gene edited therapies in development for severe SCD or TBT. The most advanced of these is Bluebird bio's Zynteglo (beti-cel, betibeglogene autotemcel, formerly LentiGlobin) for TDT which was FDA approved in August 2022. Bluebird bio's SCD candidate lovo-cel (lovotibeglogene autotemcel, also formerly LentiGlobin) is currently in Phase III and the subject of an FDA partial clinical hold in paediatric patients; however, the company is guiding to BLA filing in Q123. A number of programmes are under evaluation in Phase I/II studies, such as EDIT-301 (Editas Medicine; RUBY in SCD and EDITHAL in TDT), GPH101/nula-cel (nulabeglogene autogedtemcel, Graphite Bio; CEDAR in SCD), SAR445136 (formerly also BIVV003, Sangamo Therapeutics; Precizn-1 in SCD), OTQ923/HIX763 (Intellia Therapeutics/Novartis; Phase I/II in SCD), and ARU-1801 (Aruvant Sciences; MOMENTUM in SCD).

Competitive and clinical issues will take time to clarify

This level of competition in a relatively small market, coupled with potential concerns about safety, durability, and pricing/reimbursement provide a bear case that gene edited therapies will not disrupt the SCD and TDT markets as uptake will be more modest, and certainly not Trikafta-like. We believe such concerns are behind the fall in exa-cel value as assessed by Evaluate Pharma's Omnium NPV Analyzer which ascribes a $3.2bn rNPV (or $6.2bn unadjusted NPV), roughly 50% lower than a year ago. Evaluate's exa-cel sell-side consensus sales for 2028 across both indications are now $707m.

Long-term clinical data may be needed to establish clinical roles and appropriate pricing

In our view, much of this caution stems from concerns about durability and pricing/reimbursement. Approved gene therapies, especially when 'one-and-done', command high prices, although outcomes-based rebates may be agreed based on long-term durability measures. Durability of exa-cel appears promising to date with data presented at EHA 2022 indicating 95% efficacy in TDT with 42 out of 44 patients transfusion free with a follow-up of 1.2 months to 37.2 months (95% efficacy). In SCD, all 31 patients treated were free of vaso-occlusive crises (100% efficacy) with follow up of 2.0 months to 32.3 months. However, data in a larger population, and real-world data may be required to support pricing.

Funding agencies/payors have to be convinced of clinical value...

The most relevant proxy for exa-cel is Bluebird bio's beta-globin gene therapy Zynteglo for TDT, which has had mixed fortunes. Zynteglo received conditional marketing authorisation from the EMA in May 2019 and was launched in Europe priced at €1.6m ($1.8m) as part of a proposed value-based payment model. Push

back was received from European reimbursement authorities, including the German Federal Joint Committee (G-BA) and UK's National Institute for Health and Care Excellence (NICE), as the price was considered too high. Subsequently, in August 2021, Bluebird bio announced that it would wind down its European operations and withdrew Zynteglo MAAs from the EU and UK in early-2022.

...with different outcomes in US and Europe so far

The situation appears rosier in the US, where the FDA approved Zynteglo in August 2022 following an unanimously positive June 2022 FDA AdCom (13-0 that beti-cel's benefits outweighed any risks, in particular cancer risk associated with the lentivirus vector). Here, the US Institute for Clinical and Economic Review (ICER) indicated that bet-cel is cost effective at $2.1m 'through a five-year outcomes-based contract for patients with sustained transfusion independence'. Bluebird bio subsequently announced a list price of $2.8m for Zynteglo with an outcomes-based contract that includes a single upfront payment and up to 80% risk-sharing if a patient fails to achieve/maintain transfusion independence up to two years post-infusion.

MaxCyte will benefit, the real question being by how much?

At this stage, it is too early to speculate on pricing and reimbursement strategies for exa-cel or other programmes enabled under a MaxCyte SPL. However, if clinical development is successful, and approval is granted, it is reasonable to expect that novel cell and gene therapies such as exa-cel will be expensive in absolute terms, providing that the pricing is supported by compelling health economics outcomes data. Manufacturing is one aspect that will also contribute to this; we highlight that MaxCyte's non-viral approach has cost, speed, and scalability advantages over viral transfection, which could have positive implications for COGS and the time to treat patients.

Meanwhile, internal hedges reduce overall risks

We note that Editas Medicine's EDIT-301 is covered under a MaxCyte SPL, as we believe are two programmes that Beam Therapeutics is developing for SCD: BEAM-101 (Phase I/II BEACON-101 start in H222) and BEAM-102 (preclinical). With four SCD and two TDT programmes under three SPLs, MaxCyte has an internal hedge in these indications which diversifies its development, regulatory, commercial, and competitive risks in these indications.

Valuation and Financials

Our valuation is now £980m ($1.27bn) or 964p / $12.53 per share

Our MaxCyte sum-of-the-parts valuation model includes a three-phase DCF of recurring revenues from the core business, an NPV of potential pre-commercial milestone revenues, and a pipeline rNPV of potential royalties/sales-based payments from the most advanced programmes (where consensus sales are available via Evaluate Pharma). Our new valuation is £980m ($1.27bn) or 964p / $12.53 per share vs £1.06bn ($1.39bn) or 1,050p / $13.64 per share previously.

Valuation update reflects new guidance, partner disclosures, and revised consensus

Following Q222 results, we make minor adjustments to our forecasts given updated management guidance, which flow through to our Core business DCF. We have also revisited our SPL pipeline rNPV model to reflect latest disclosures from SPL partners and most recent consensus sales. Risk adjustments reflect the phase of clinical development but have been flexed upwards if preliminary data is available. Discontinuation of CTX120 means it has been removed from our pipeline rNPV model, while three programmes have been added (ALLO-306, CB-010, BEAM-101) as consensus forecasts are now available. We continue to ascribe a modest placeholder value for the undisclosed SPL assets and the 20+ SPL programmes which we have identified that are on the cusp of the clinic or IND filing, but where there is currently limited visibility.

Pricing/reimbursement concerns impact peak sales expectations

We highlight that the primary contributing factor to our lower pipeline rNPV is the downgrades to consensus peak sales expectations across the pipeline. In our view, this is indicative of the uncertainty surrounding pricing and reimbursement, firstly of 'one-and-done' therapies for genetic disease, and secondly for allogeneic cell therapies where consistent durability is yet to be demonstrated. The impact of these lower consensus sales is outside of MaxCyte's control and is partially offset by the upgrade to core business valuation reflecting its strong performance.

Conservative approach leaves room for upside from strategic execution

Exhibit 5 provides an overview of the various components in our SOTP model: more detail on methodology and underlying assumptions is available in our March 2022 Outlook. Exhibit 6 details the SPL assets explicitly valued in our pipeline rNPV. We continue to employ a conservative valuation approach which leaves ample room for upside as MaxCyte continues to execute on its strategy.

Exhibit 5: Sum-of-the-parts valuation model of MaxCyte

Cashflow	Notes	rNPV ($m)	rNPV (£m)	rNPV/share ($)	rNPV/share (p)
Core Life Sciences division (no milestones)	Three phase DCF: Core sales growing at CAGR of 26% from $31.4m in FY21 to $98.0m in FY26E, then trending to 3% growth. Operating margin growing to c 30% in FY35E. Terminal growth rate of 2%	242.6	186.7	2.39	183.5
SPL pre-commercialisation milestones	Based on 112 programmes (all potentially entering the clinic by 2028), each risk-adjusted, with $10m in pre-commercialisation milestones	166.7	128.3	1.64	126.1
SPL sales-related revenues	Assumes receipt of a blended 2% royalty (to capture the single-digit sales royalty or milestone equivalent and a proportion of volume-based consumable use)	623.6	479.7	6.13	471.7
Net cash	As at end-Q222 (30 June 2022)	240.9	185.3	2.37	182.2
Total		**1273.9**	**979.9**	**12.53**	**963.5**

Source: Trinity Delta Note: discount rate of 10% for Life Sciences business; 12.5% for milestones and royalty stream; 35% tax rate from 2024, and $1.30/£1 FX rate

Exhibit 6: Indicative rNPV of royalty streams from programmes assumed to be under licence

Partner	Programme	Indication	Stage	Risk adjustment	rNPV ($m)	rNPV (£m)	rNPV / share ($)	rNPV / share (p)	Notes
CRISPR Therapeutics	CTX001	SCD/ß-thalassemia	Phase III	75%	21.3	16.4	0.21	16.10	Peak sales: $1.15bn. Launch year: 2023
	CTX110	B cell malignancies	Phase II	45%	16.6	12.7	0.16	12.53	Peak sales: $1.0bn. Launch year: 2024
	CTX130	RCC / B cell maligancies	Phase I	20%	1.1	0.9	0.01	0.85	Peak sales: $350m. Launch year: 2025
Allogene Therapeutics	ALLO-715	r/r MM	Phase I	20%	11.9	9.1	0.12	8.99	Peak sales: $1.3bn. Launch year: 2024
	ALLO-501	r/r NHL	Phase II	25%	8.1	6.2	0.08	6.11	Peak sales: $1.0bn. Launch year: 2024
	ALLO-316	RCC	Phase I	15%	0.8	0.6	0.01	0.60	Peak sales: $175m. Launch year: 2027
Editas Medicine	EDIT-301	SCD/ß-thalassemia	Phase I/IIa	15%	5.4	4.2	0.05	4.11	Peak sales: $1.0bn. Launch year: 2024
Precision BioSciences	PBCAR0191	r/r NHL / B-ALL	Phase I/IIa	25%	3.6	2.7	0.03	2.69	Peak sales: $475m. Launch year: 2024
	PBCAR269A	r/r MM	Phase I	15%	2.1	1.6	0.02	1.58	Peak sales: $500m. Launch year: 2025
Caribou Biosciences	CB-010	r/r B-cell NHL	Phase I	20%	2.8	2.1	0.03	2.09	Peak sales: $400m. Launch year: 2024
Beam Therapeutics	BEAM-101	SCD	Phase I	15%	2.8	2.1	0.03	2.09	Peak sales: $400m. Launch year: 2024
Various	Other	Various	IND +	-	547.3	421.0	5.38	413.9	Numerous progs
Total					**623.6**	**479.7**	**6.13**	**471.7**	

Source: Trinity Delta, Evaluate Pharma. Note: Launch dates and revenue forecasts based on consensus forecasts obtained from Evaluate Pharma (accessed 15/8/22)

Strong revenue growth continued into Q222

MaxCyte reported Q222 revenue of $9.6m (+35% y-o-y; Q221: $7.1), mainly supported by the strong growth of 61% in the Cell Therapy business generating revenue of $7.7m (Q221: $4.8m). Drug Discovery revenues grew more modestly, up 4% to $1.9m (Q221: $1.8m), while there was no material Programme-related revenue (Q221: $0.5m). These figures highlight both the continuing growth in sales and licence of instruments and high-margin disposable sales in the core business (Q222 core revenues up 48% to $9.6m vs $6.6m in Q221), and the inter-period variability seen with individual milestone triggering events at SPL partners. Q222 gross profit was $8.5m (Q121: $6.3m), representing a gross margin of 88% (Q121: 89%).

Driven by underlying growth and little in SPL-related fees

For H122, total revenue stood at $21.2m (+56% on H121: $13.6m), with Cell Therapy revenue growth of 59% to $15.1m (H121: $9.4m), Drug Discovery growth of 13% to $4.1m (H121: $3.6m), and Programme-related income of $2.0m vs $0.5m in H121. Gross profit for H122 was $19.0m vs $12.1m in H121, with a gross margin of 90% vs 89% respectively.

Second raise in FY22 guidance

MaxCyte's core business generates a high proportion of recurring income, and this visibility has prompted management to raise FY22 guidance for the second time this year. Latest guidance is for approximately 30% growth in core business revenue, vs at least 25% at the time of Q122 results and 23-25% when FY21 reported. The expectations for programme-related revenues from SPL milestones remain at c $4m for FY22.

Continuing to invest in ensuring the right platform is in place

Higher operating costs reflect the investments that MaxCyte is making to support future growth, and the goals of its customers and partners. This includes increased headcount, particularly in field sales and science, manufacturing, and lab teams. Q222 operating expenses stood at $17.2m (Q221: $10.7m). S&M costs increased to $4.9m (Q221: $2.9m), with higher G&A of $7.1m (Q221: $4.3m) partly due to NASDAQ public company expenses and compliance costs. R&D investment grew to $4.7m (Q221: $3.2m). Q222 net loss was $8.3m vs a $4.4m net loss for Q221.

Rising expenses reflect the size of the commercial opportunities

H122 total operating expenses were $31.9m (H121: $22.9m). S&M costs rose to $8.8m (H121: $5.7m), with G&A also up at $13.7m (H121: $7.3m); however, R&D spend fell to $8.5m (H121: $9.3m) as the first quarter in the prior period included CARMA-related spending (this ceased from March 2021 onwards). H121 net loss was $12.3m vs a net loss of $11.5m in H121.

Well-funded to support the core strategic priorities

MaxCyte remains well-funded, with modest cash burn despite increased investment across several areas. End-June 2022 total cash, cash equivalents and short-term investments was $240.9m. The company intends to invest further in R&D, manufacturing, and headcount in order to support the needs of existing partners as they approach commercialisation (eg in-house manufacturing scale up, regulatory field support) as well as facilitating expansion into potential new applications and markets. These strategic activities, the continuing rapid growth in cell therapy R&D, and growing demand for MaxCyte's enabling technologies should support future core business revenue growth as well as potentially add further SPL partners. Management has indicated their belief that end-December 2022 cash resources will be c $220m, and that they remain comfortable with an expectation that three new SPLs are secured each year (two have been signed so far in 2022).

New forecasts indicate higher revenue growth and maintenance of pharm-like margins

Exhibit 7 summarises changes to our financial forecasts. We model FY22 revenues of $44.9m, with $40.9m from the core business (+30% on FY21) and $4.0m of Programme-related revenues. For FY23, these figures are $57.7m, $50.7m, and $7.0m respectively. Gross margin expectation for both periods is 90%. In our March 2022 Outlook we attempted to assess near-term milestone potential over the 2022-23 period from identified pipeline assets based on SPL partner disclosures. However, due to the lack of visibility on precise milestone trigger points and timing of receipts, plus the dependence on programme progress and decisions at SPL partners, we apply a risk-adjustment to our figures for programme-related revenues.

Net loss in FY22 and FY23 reflects continued investment for revenue growth

Continued investment to drive revenue growth means we expect FY22 R&D, S&M, and G&A to increase to $23.4m, $23.4m, and $26.1m respectively. For FY23, we forecast R&D of $30.4m, S&M of $24.2m, and G&A of $30.8m. This translates into a FY22 net loss of $34.8m, and a $36.7m net loss in FY23.

Exhibit 7: Summary of changes to estimates

	Revenues ($m)			Adj. EBITDA ($m)			Adj. EPS (c)		
	Old	New	Change	Old	New	Change	Old	New	Change
2022E	42.6	44.9	5.4%	(22.3)	(24.5)	(9.9%)	(32.3)	(34.4)	(6.5%)
2023E	54.9	57.7	5.1%	(25.5)	(25.2)	1.2%	(36.4)	(36.0)	1.1%

Source: Trinity Delta

Exhibit 8: Summary of financials

Year-end: December 31	$m	2019	2020	2021	2022E	2023E
INCOME STATEMENT						
Revenues		**21.6**	**26.2**	**33.9**	**44.9**	**57.7**
Cost of goods sold		(2.5)	(2.8)	(3.6)	(4.7)	(5.8)
Gross Profit		**19.1**	**23.4**	**30.2**	**40.2**	**51.9**
R&D expenses (excluding CARMA)		(5.9)	(6.6)	(11.1)	(23.4)	(30.4)
R&D expenses (CARMA)		(11.7)	(11.1)	(4.3)	0.0	0.0
Sales and marketing expenses		(7.9)	(8.3)	(13.0)	(23.4)	(24.2)
General and administrative expenses		(5.6)	(7.4)	(18.7)	(26.1)	(30.8)
Depreciation and amortisation		(0.5)	(1.0)	(1.3)	(2.3)	(3.3)
Underlying operating profit		**(12.4)**	**(11.1)**	**(18.2)**	**(34.9)**	**(36.8)**
Underlying operating profit (excluding CARMA)		**(0.7)**	**0.0**	**(13.9)**	**(34.9)**	**(36.8)**
Other revenue/expenses		0.0	0.0	0.0	0.0	0.0
Adj EBITDA		**(10.1)**	**(7.5)**	**(8.8)**	**(24.5)**	**(25.2)**
Adj EBITDA (excluding CARMA)		**1.6**	**3.6**	**(4.5)**	**(24.5)**	**(25.2)**
Operating Profit		**(12.4)**	**(11.1)**	**(18.2)**	**(34.9)**	**(36.8)**
Interest expense		(0.5)	(0.8)	(0.9)	0.1	0.2
Profit Before Taxes		**(12.9)**	**(11.8)**	**(19.1)**	**(34.8)**	**(36.7)**
Adj. PBT		**(12.9)**	**(11.8)**	**(19.1)**	**(34.8)**	**(36.7)**
Current tax income		0.0	0.0	0.0	0.0	0.0
Cumulative preferred stock dividend		0.0	0.0	0.0	0.0	0.0
Net Income		**(12.9)**	**(11.8)**	**(19.1)**	**(34.8)**	**(36.7)**
EPS (c)		**(22.9)**	**(17.0)**	**(4.8)**	**(34.4)**	**(36.0)**
Adj. EPS (c)		**(22.9)**	**(17.0)**	**(4.8)**	**(34.4)**	**(36.0)**
DPS (c)		**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)		56.4	69.5	100.8	101.3	101.7
Gross margin		*88%*	*89%*	*89%*	*90%*	*90%*
BALANCE SHEET						
Current assets		**24.5**	**45.3**	**270.4**	**241.2**	**212.0**
Cash and cash equivalents		15.2	18.8	47.8	94.8	101.4
Short-term investments		1.5	16.0	207.3	127.3	87.3
Accounts receivable		3.2	5.2	6.9	9.1	11.7
Inventories		3.7	4.3	5.2	6.7	8.3
Other current assets		0.8	1.0	3.3	3.3	3.3
Non-current assets		**5.5**	**6.5**	**13.7**	**17.1**	**19.8**
Property, plant & equipment		3.3	4.5	7.7	11.1	13.8
Other non-current assets		2.3	2.0	6.0	6.0	6.0
Current liabilities		**(9.3)**	**(11.6)**	**(15.6)**	**(16.5)**	**(18.4)**
Short-term debt		(0.5)	(0.6)	(0.5)	(0.5)	(0.5)
Accounts payable		(5.6)	(6.2)	(8.3)	(7.7)	(8.0)
Other current liabilities		(3.2)	(4.8)	(6.7)	(8.2)	(9.9)
Non-current liabilities		**(7.0)**	**(6.9)**	**(5.6)**	**(5.6)**	**(5.6)**
Long-term debt		(4.9)	(4.9)	0.0	0.0	0.0
Other non-current liabilities		(2.1)	(2.0)	(5.6)	(5.6)	(5.6)
Equity		**13.6**	**33.2**	**262.9**	**236.2**	**207.8**
Share capital		97.0	128.4	377.2	377.2	377.2
Other		(83.4)	(95.2)	(111.0)	(141.0)	(169.4)
CASH FLOW STATEMENTS						
Operating cash flow		**(8.8)**	**(8.8)**	**(10.7)**	**(27.2)**	**(27.3)**
Profit before tax		(12.9)	(11.8)	(19.1)	(34.8)	(36.7)
Non-cash adjustments		2.5	3.9	9.8	10.3	11.4
Change in working capital		1.6	(0.8)	(1.4)	(2.9)	(2.3)
Interest paid		0.0	0.0	0.0	0.1	0.2
Taxes paid		0.0	0.0	0.0	0.0	0.0
Investing cash flow		**0.5**	**(16.6)**	**(195.0)**	**74.2**	**34.0**
CAPEX on tangible assets		(1.3)	(2.1)	(3.8)	(5.8)	(6.0)
Other investing cash flows		1.7	(14.5)	(191.2)	80.0	40.0
Financing cash flow		**12.3**	**28.9**	**234.7**	**0.0**	**0.0**
Proceeds from equity		12.5	29.0	236.1	0.0	0.0
Increase in loans		(0.2)	(0.1)	(0.1)	0.0	0.0
Other financing cash flow		0.0	0.0	(1.3)	0.0	0.0
Net increase in cash		**4.0**	**3.5**	**29.0**	**47.0**	**6.6**
Cash at start of year		11.2	15.2	18.8	47.8	94.8
Cash at end of year		**15.2**	**18.8**	**47.8**	**94.8**	**101.4**
Net cash at end of year		**11.3**	**29.3**	**254.5**	**221.5**	**188.1**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. No new SPLs are included in our forecasts.

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