Global Pharmaceuticals Insights on US Plasma Donations & Updates on Plasma Derived Therapies for COVID-19

Major Pharmaceuticals | Connections Series

In this connection series note, we provide insights on the current state of plasma collection in the US, and an update on the latest development for plasma derived therapies against COVID-19 as it relates to the three largest players in plasma derived therapeutics: Grifols (EU pharma team), CSL (Gretel Janu, Australian equities) and Takeda (Sakai-san, Japanese Pharma). We also highlight coverage of CBPO (FY 19 results comment) where our team noted a 1 month plasma collection suspension in China and slow recovery.

- Limited disruption to US Plasma collection observed so far, but may follow in near term as COVID-19 outbreak continues to grow in US. (Most 1Q impact felt by Grifols likely to be in Germany, given the need for an onsite doctor). Most investor focus has been on the Mexico border, although this is still open to plasma donors who are deemed essential. For Grifols CS est. c.5% of sites c.8% of global capacity. A move of COVID-19 hot spots to the next 5 states as predicted by the Whitehouse Task Force could impact donations more. Exposure to centres here ranges from 37% TAK, 48% GRLS, & 56% CSL.
- US rising unemployment rates may increase mid term donation volumes and Grifols & CSL have the highest centre exposure to states with most jobless claims thus far (c 40%) vs Takeda (c 20%). We reflect this with higher mid term growth in our models.
- CSL is seeing "lumpy" plasma supply, but demand remains strong: In March, CSL saw its US plasma collections soften but remain above the prior year's level. However, in the last few weeks, CSL did see volumes dip further, with collections falling below the levels achieved in prior periods (CSL research note). We forecast CSL's FY20 plasma collections down 8%vs pre-COVID-19 estimates, and forecast 13% IG revenue growth (previously 17%). We've reduced our FY21 EPS estimates a total of 8% as a result of COVID-19 disruption to CSL's plasma supply.
- In a companion <u>note</u> we have cut our Grifols FY20 EPS by 2%, FY21 by 6% and raised FY22 by 6%. This reflects 2% lower plasma collection volume in 1Q'20, -15% in 2Q, and -3% in 3Q with a rebound of +6% in 4Q20. The EPS hit comes with a 6-9month lag to from collection to sales. Our change in collection growth broadly matches our CSL assumptions on donation volumes, but are less marked overall, reflecting the limited expectation of new openings for Grifols vs expectations for both CSL and Takeda.
- Hyperimmune immunoglobulin (H-IG) to be available for testing in COVID-19 patients as early as July. Grifols may be first to patients with its H-IG, in collaboration with FDA/BARDA (where it can utilise a dedicated fractionation plant). CSL and Takeda have simultaneously formed an alliance with additional companies to accelerate development of an unbranded H-IG therapy, however, timelines have not been disclosed. We estimate c75 donors' plasma will produce therapy to treat 3-4 patients.
- Convalescent plasma already being utilized in small patient numbers following the FDA authorizing its emergency use. Collection of plasma from recovered COVID-19 patients has begun primarily in the hospital setting.

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Executive Summary

There are 4 key plasma manufacturers under Credit Suisse coverage, CSL, Grifols, Takeda (who acquired Shire) and China Biological Products. Collectively we estimate sales of plasma derived products/therapies of c USD \$15 billion in 2019, and expect this to grow to c\$21 billion by 2023 (see Figure 1). Of these total sales estimates, c60% of revenues come from immunoglobulin products, c15% from albumin and the remaining 25% comes from other proteins.

In this report, we present insights on the initial impact felt from COVID-19 on plasma collection, and provide sensitivity analysis for three key players and give an update on the latest development on plasma derived COVID-19 therapies.

CSL

- CSL updated the market on 9th April on how it has been impacted by COVID-19 (<u>CSL</u> research note)
- Plasma collections: In March, CSL did see collections soften but remain above the prior year's level. In the last few weeks, CSL did see collections dip further, with collections falling below the levels achieved in the pcp. Collections in the various centres are mixed and lumpy. Some centres are achieving collections above budget, other centres have seen a material slowdown.
- Centres along the US/Mexico border have been impacted by the border closure. Mexicans are still allowed to donate, but the greater restrictions in crossing the border have created some slowdown. CSL has ~4% exposure to US/Mexico border.
- CSL is still expecting to open 40 new collection centres in FY20 (currently have opened 32 centres). New donors are expected to arise following the economic downturn, but CSL will likely have to increase advertising to get access to new donors.
- Strong demand for products remains as they are life -saving & life -extending and usually non-discretionary. In particular, CSL has seen increased demand for IVIG from hospitals.
- Despite CSL remaining positive that it will be able to open the remaining 8 collection centres in FY20, we prefer to remain conservative. We forecast no further plasma centre openings in FY20 (a total of 32 centres in FY20). We assume total plasma collected in FY20 is 17mn litres (down 8% from prior estimate of 18.3mn L). This implies that the plasma collected between April-June is ~16% below the monthly average seen in 1H20 and January & February 2020. We continue to believe that as soon as the US economy begins to open following peak infections we will see a sharp increase in plasma collections due to the rising unemployment rate.
- We assume IG revenue growth of 13% in FY21, following 21% IG revenue growth in FY20. We forecast 50bp gross margin contraction in CSL Behring in FY21 due to added collection costs associated with COVID -19.

Grifols

- Primary research insights from 6 Grifols collection centres shows some initial signs of disruption from COVID-19, with centres working under reduced capacity, due to social distancing requirements and staffing shortages.
- We see Grifols as having the highest exposure to the temporary closure of the US-Mexico border, where it has c5% of its sites (which we estimate contribute c8% of its plasma volumes). We understand donors can still cross the border, as are deemed essential, but in our view we estimate there may still be negative impact in the near term.
- Grifols sits between peers in terms of % of sites exposed to US states with the highest rates of confirm COVID-19 infections. We see this as a potential risk to near term donation volumes. However we see Grifols as well positioned in US states with the highest rates of



new unemployment filings thus far, where it could see an uplift in new donors in months to come.

- In a companion note we have updated our Grifols model assuming 15% lower plasma collection in 2Q, and 3% in 3Q with a rebound of +6% in 4Q, driven by new donors likely to be attracted by the donor fee with higher levels of unemployment. With a 6-9 month lag to sales, and a 70% contribution margin this would suggest a- 2% impact on 2020 EPS and 6% on FY2021 EPS but an increase of 6% in 2022 EPS with higher long term donations. Grifols has seen a strong increase in number of collection centres up from 190 at the end of 2017 to 295 at the end of 2019 and we assume only c 7 new openings in 2020. Grifols is also able to access more plasma from acquired sites which are winding their third party sales, making more available to Grifols. This potentially puts Grifols in a better position than peers who need to both drive up donations per site and open new sites which may be challenging. This analysis does not take into account any ability to supply more albumin to China in 2H2020 if local players who have also had temporary collection issues find themselves short of inventory in 2H2020/early 2021. We understand that Grifols current inventories are at least 6 months giving them some likely flexibility to take advantage of any market shortages. Neither does it reflect higher prices likely during market shortages or potentially lower donor fees possible if economic pressures increase the number of donors
- The company is actively working with the FDA/BARDA on the development of both a hyperimmune immunoglobulin (H-IG) product to treat COVID-19 as well as convalescent plasma, where it has the possibility to be first to patients with the former. Grifols is aiming to have its H-IG available by July, and convalescent plasma ready for use in 2-3 weeks time.

Takeda

■ Takeda acquired Shire within which lies the old Baxalta plasma unit. Under the direction of Julie Kim who joined with Shire, Takeda is looking to expand its plasma collection centers but has noted that low site numbers relative to sales correctly suggests high efficiency and larger average sites today. A sensitivity discussed later in the report that matches the Grifols assumptions would result in a -2% for EPS for Fiscal FY21 and +2% in Fiscal 22. This assumes a 70% contribution margin on lost / gained sales and a 15% tax rate. This sensitivity ignores any pricing impact from shortages, or material additional demand from COVID related hyper immune or convalescent plasma sales. For our analysis Takeda has the lowest exposure of the majors to sites near the Mexican border ,and the lowest exposure the next 5 states hightailed as likely to be next hot spots in the US by the White House task force.

CBPO

- COVID-19 brings uncertainty to 2020E. Plasma collection was suspended for more than one month and just resumed starting in early March, but the recovery speed is low. CBPO postponed giving 2020 guidance. We expect 2020 top line/bottom line to grow at ~10%. CBPO has several months of plasma inventory to maintain production.
- On a China wide industry-level, blood products, especially IVIG usage, during COVID-19 increased, and our team assumes that at some point imported human albumin supply might be reduced by the COVID-19 outbreak in EU/US. As a result, our team expects both human albumin and IVIG supply to be constrained and prices to increase in 2020.



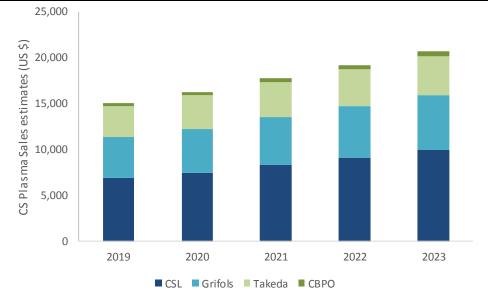


Figure 1: CS Plasma sales forecasts for 4 key players, 2019-2023e

Source: Company data, Credit Suisse estimates



Current status of US Plasma Collection

The US is the largest market for plasma collection, with >700 plasma donation centres spread across the country, making up the majority of worldwide plasma collections in volume. Of those centres, 246 belong to CSL, 250 are Grifols' and 126 are owned by Takeda (Biolife). For Grifols, we estimate >70% of its supply is sourced in the US, and understand that 85-90% of which is collected directly by Grifols (the remaining is bought in from third parties). CSL sources the vast majority of plasma (~95%) from its US collection centres.

The US plasma market is also unusual in that it compensates its donors, paying them somewhere between c\$45-70/donor (depending on volume given/weight of donor and company paying). We estimate a typical US donor fee of \$50/donation (based on our CSL discussions, but note that Grifols has suggested a slightly lower effective figure in the range of \$45-50/litre. We estimate average donation volume is 0.8L.

Given the US is swiftly becoming the epicenter of the coronavirus outbreak (c>400,000 cases of global c1.4m cases), we conducted primary research through talking to donation centres and looked at the relative exposure to the three companies under our coverage by regions most heavily affected by the virus. We have also conducted a sensitivity analysis for Grifols, Takeda and previously published one for CSL (link) on the potential impact of COVID-19 to supply and costs.

Donors may use plasma donation as an additional source of monthly income, so we see this as a potentially attractive earning opportunity to some in the US, given the rising rates of individuals filing for unemployment benefits. Latest data from the US Department of Labor has <u>reported</u> c6.4million seasonally adjusted initial claims for unemployment made as of 2nd April 2020, up from the previous week's level of c3.3million

Primary research from US collection centres shows initial signs of disruption due to COVID-19

We recently contacted 21 US donation centres and spoke with 18 of them, 6 from each company (CSL, Grifols, Takeda), across the following states Texas, Arizona, Washington, California, New Jersey and Colorado.

- Reduced capacity due to CDC guidelines/social distancing. Most centres appear to remain open at this time. Both Grifols and Takeda centres explicitly indicated they are operating under reduced capacity, due to social distancing measures and recently updated CDC guidelines for blood/plasma collection (link), which advises centres to have at least 6 feet between donor chairs. They did not quantify the level of restriction.
- Restricted hours due to capacity. Some centres noted they are open for restricted hours (e.g. only open until 2pm vs usually open until 8pm) due to staff shortages (partially due to self-quarantining).
- Less appointment availability in hotspots. Centres closer to COVID-19 hotspots, such as Washington state or New Jersey appeared to have less availability for appointments for new donors and are operating under restricted hours.
- Minimal centre closures to date. Some centers we tried to reach were closed. We understand Grifols may be temporarily closing some centres if there are issues and may at some point to have to shut down a handful of centres due to COVID-19, however we view these as only temporary closures. We understand CSL had to temporarily close a centre in Florida after one of the staff members contracted COVID-19. Yet CSL was able to re-open the centre in just a few days.

We understand that Grifols and CSL have both started to see a reduction in capacity (due to social distancing measures/reduced hours) but that this can be partially offset through better management of its network, booking donors appointments in advance and increasing operation hours (i.e. more donors coming early mornings/later in the evenings).



US state by state analysis shows CSL with the greatest exposure to the COVID-19 "hot spots"

As of April 9th, John Hopkins data indicate there are c. 432,000 confirmed coronavirus cases in the United States. Of those cases, the majority are within top ten states, New York, New Jersey, Michigan, California, Louisiana, Florida, Massachusetts, Illinois, Pennsylvania and Washington.

Bloomberg has reported that the White House task-force coordinator Deborah Birx has indicated that the rate of positive coronavirus tests suggest the next "hot spots" in the US could include Michigan, Connecticut, Indiana, Georgia and Illinois. We would expect these hot spots may cause greater short term disruption to plasma collection, potentially reducing short term donation volumes.

Based upon this, we present the relative exposure of collection centres in the top 15 affected states by company (see Figure 2) CSL appear to have the greatest exposure overall to the top 15 states and has the largest number of sites in the expected upcoming "hot spot" states.

Figure 2: Number of company collection centres in 15 US states with highest rates of COVID-19 confirmed cases

	CSL	Grifols	Takeda
1 New York	10) 0	0
2 New Jersey	4	0	0
3 Michigan	19) 10	5
4 California	C) 11	0
5 Louisiana	Э	8 7	0
6 Florida	17	' 16	4
7 Massachusetts	C) 0	0
8 Illinois	1C) 8	4
9 Pennsylvania	10) 7	1
10 Washington	5	i 4	3
11 Georgia	ç) 11	7
12 Texas	32	2 33	10
13 Connecticut	C) 0	0
14 Colorado	7	77	3
15 Indiana	11	7	7
Total	137	' 121	44
% of Total US sites	56%	48%	37%

Source: Company data, Credit Suisse estimates, John's Hopkins

US-Mexico Border restrictions most likely to cause short-term disruption to Grifols US plasma collection

Whilst not disclosed by the companies, we estimate somewhere between 40-80% of donors at plasma collection sites close to/on the US-Mexico border, have crossed over from Mexico on a temporary visa to donate plasma. As of March 20th, the US <u>enforced</u> travel restrictions on the Mexico border, limiting travel of individuals to essential travel only until April 20th at this time, but we could expect the restrictions could be in place longer given the acceleration of new coronavirus cases being seen in the US. This news has attracted investor attention, as both CSL and Grifols have a number of plasma donation centres which sit very close to the Mexico border, across multiple states (California, Arizona and Texas). Whereas Takeda does not have any sites in these locations.



- Grifols has the largest exposure to potential impact from these travel restrictions on the border, with 16 of its US centres in the affected location (representing c5% of its global sites, and we estimate c8% of global volume). We estimate CSL has ~5% exposure to the border. We understand that US homeland security have classified plasma donors as essential travelers so are still allowed to cross the border but expect travelling/entry into the US to be more challenging for donors and so these donor sites may see less donors in the near term. We understand that Grifols have seen a reduction in collection volumes in March compared with Jan/Feb at these sites, however view it as too early to confirm the level of this decline or how long it will last.
- Primary research suggests more openings for new donor appointments at these sites. At the end of last week, we spoke with a handful of Grifols and CSL centres that are located near the border, who confirmed their sites are remaining open as usual for collection at this time. We note that these sites had appointment availability for new donors within 24-72 hours of the phone call, which contrasts sites we spoke to elsewhere in the US which had much less availability. We highlight that Grifols collection centres close to the border produce greater than average volumes of plasma, so we estimate them to have an overall larger capacity for number of donors. This may in part account for the near term availability of appointments at the sites we spoke with.

Figure 3: Number of US plasma collection sites closest to Mexican border by company

Company	Total US centres	Sites close to Mexican border
CSL	246	11 (4%)
Grifols	250	16 (5%)
Takeda	120	0 (0%)

Source: Company data, Credit Suisse estimates

New centre openings likely to stall for all three players

As a result of COVID-19 lockdowns, we expect new centre openings to stall. CSL is targeting the largest number of new collection centre openings in FY20, with 40 new collection centre planned. We estimate that Grifols could open c 7-10 new centres within 2020 (based on Grifols target of reaching 321 centres by 2022). Takeda opened 19 new collection centres in 2019, and we expect the same level of investment in 2020 and beyond, in order to catch up on demand. (Takeda is investing to grow its plasma collection capacity by >65% over the next 5 years).

In 2020 YTD, CSL has opened 12 centres vs Grifols and Takeda opening 2 and 3 centres each, respectively, according to the FDA. Relative to the other players, opening new plasma centres has been a core strategy for CSL in growing its plasma supply. A potential 3-6 month delay to openings could have greater implications for its growth potential over the short-medium term (Figure 4 and Figure 5).



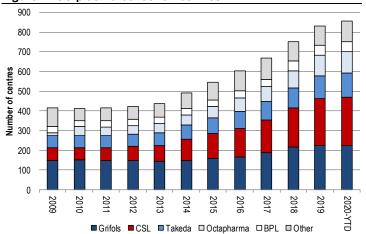


Figure 4: US plasma collection centres



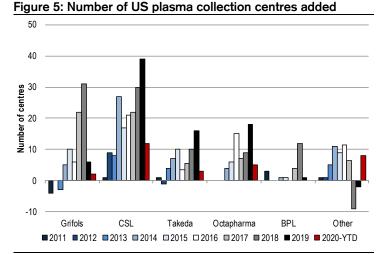
Source: FDA, Company data, Credit Suisse estimates

Rising unemployment rates in the US; CSL and Grifols positioned for an uplift in new donors

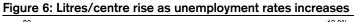
Whilst we see a risk to short term plasma collection volumes due to COVID-19 disruption to normal day-to-day business and operations, rising unemployment rates may lead to increased supply later in the year, since plasma donors can be financially compensated.

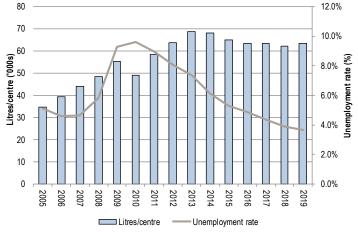
Following the global financial crisis, when rates of US unemployment rose rapidly in the US, we saw average litres collected/centre also grew (+14% in 2009), according to the PPTA. 2010 saw a decline due to increased supply, yet this was quickly reversed with collections/centre rising up to ~70k L/centre in 2013 normalizing back to ~62k L/centre as the unemployment rate fell from 6% to <4% between 2014-19. Given the strength in demand, where demand continues to exceed supply, we do not believe we will get into a situation similar to 2010 where there was excess supply in the market.

In the last two weeks of March, we have seen a spike in the number of Americans who have filed for unemployment benefits (see Figure 6) and could expect these numbers to continue to grow. In the 10 states that have recorded the largest number of initial jobless claims so far, CSL and Grifols have similarly high exposure (see Figure 9). Based upon this analysis, we see both CSL and Grifols as relatively best positioned to maintain a growing raw material supply from potential new donors in the US.

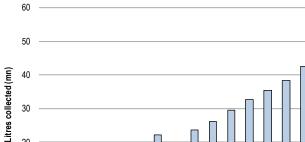


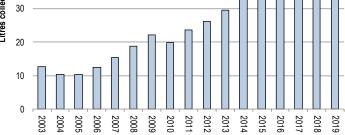






Source: US Department of Labour, PPTA, Credit Suisse Estimates





Source: PPTA, Credit Suisse Estimates

Figure 7: US plasma litres collected

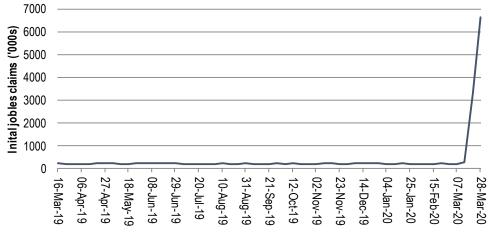


Figure 8: US initial jobless claims (weekly data)

Source: Company data, Credit Suisse estimates

Figure 9: US plasma collection sites by company in 10 US states with highest unemployment filings to date

	Unemployment filings last 2 weeks of March	CSL	Grifols	Takeda
1 California	1,065,536	0%	5%	0%
2 Pennsylvania	784,788	4%	3%	1%
3 Ohio	459,913	7%	5%	3%
4 New Hampshire	446,737	0%	0%	0%
5 Michigan	440,384	8%	4%	4%
6 Texas	431,254	12%	15%	8%
7 New Mexico	360,969	1%	0%	0%
8 Massachesetts	329,057	0%	0%	0%
9 Washington	320,979	2%	2%	3%
10 Florida	301,021	7%	7%	3%
Total	4,940,638	41%	41%	22%

Source: Company data, Credit Suisse estimates, US Department of Labor



CSL sensitivity analysis

We recently downgraded our CSL forecasts assuming modest plasma supply risk due to COVID-19 (see notes <u>CSL</u>: <u>Rising unemployment tempers plasma supply risk</u> & <u>CSL</u>: <u>COVID-19 creates lumpy plasma supply, but demand remains strong</u>). We retain an OUTPERFORM rating on the stock.

Lower collections over the next 3-6 months will affect FY21 earnings, given the ~9month production time line. We assume CSL collects 17mnL of plasma in FY20 (down 8% from prior estimate) and lowered our IG sales growth assumption to 13% in FY21. We forecast 50bp gross margin contraction in CSL Behring in FY21 due to added collection costs associated with COVID-19 and given we estimate ~20-25% of collection & fractionation costs are fixed.

We highlight the sensitivity to IG revenue growth in FY21 if:

- Collections per centre are more volatile.
- CSL is forced to close centres for up to 6 months due to COVID-19

In performing this sensitivity, we assume CSL does not open any further collection centres for the remainder of FY20 (currently has 32 centres). We estimate that for every 5 ppt decrease in collections per centre, IG revenue growth in FY21 is lowered by 100 bps. For every 5 centres that CSL closes for 6 months, we estimate this reduces IG revenue growth in FY21 by 40bps.

Figure 10: IG revenue growth sensitivity to collection centre closures and collections/centre

IG revenue g	rowth			Collections/ce	ntre (vs FY19)		
in FY21		-20%	-15%	-10%	-5%	Steady	5%
centre & no nings	0	11.9%	12.9%	13.9%	14.9%	15.8%	16.7%
-	5	11.6%	12.6%	13.5%	14.5%	15.4%	16.3%
Collection closures more ope	10	11.2%	12.2%	13.1%	14.1%	15.0%	16.0%
° ° E	15	10.8%	11.8%	12.8%	13.7%	14.7%	15.6%

Source: Company data, Credit Suisse estimates



Grifols EPS cut -2% FY20,-6% FT21,+6% FY22

In Figure 11: we show how we model plasma collection for Grifols. Historic growth has been based largely on increased collection sites with a c 13% increase in volume of plasma obtained in 2019 over 2018 coming with a 24% increase in sites (some of which aren't yet fully supplying Grifols with plasma). We have seen a 13% increase in donations, matching the volume growth. Our forecasts assume a gradual increase in effective plasma collected per site as more sites rollover to supply Grifols and as newer sites mature. In response to the current COVID situation we have updated our current assumptions cutting our assumed 1Q'20 collection volumes by 2% to reflect an impact in Germany where the need for on-site doctors may have reduced effective capacity. We have assumed a 15% drop in 2Q and a further 3% drop in 3Q which we would assume would reflect some states continuing to have issues of restricted capacity, but also some rebound especially in areas of growing unemployment. With lower economic growth we flex our numbers to show overall slightly higher volumes from 2021.

In Figure 12 we translate this to sales. We assume a 6-9 month lag between collection and the sale of the fractionated final products (IG, albumin, factor 8 alpha anti trypsin etc). At the profit level we assume a 70% contribution margin on gained /lost sales. This results in a 2% reduction in FY2020, a 6% reduction in 2021 and a 6% increase in 2022 for EPS.

For CSL CS assume an overall 8% decline in collection volumes for fiscal'20, with 1Hfiscl 2020 largely unaffected we are assuming essentially -16% in 2H, (crudely -10% in Cal 1Q and -22% in 2Q). For 1H fiscal '21 for CSL CS has assumed a 5% rebound this is slight more optimistic than the - 3% and +6% for Cal 3Q and 4Q 2020 we assume for Grifols. A major pater of the CSL assumption changes comes from reduced new site opening and the fact that CSL has not yet collected plasma from any of the 32 sites so far opening in fiscal 2020

We make no assumptions on any possible increased sales into China of albumin in 2H2020 which may occur if local suppliers have been unable to sustain local donations and no assumption of any price rises that might offset some volume loss with tight market supply which will impact all of the major players. We have not assumed lower prices from broadly increased supply post 2021 if economic conditions result in a significant increase in donors, or accounted for possibly lower donor fees that might need to be paid if donor numbers increase rapidly.

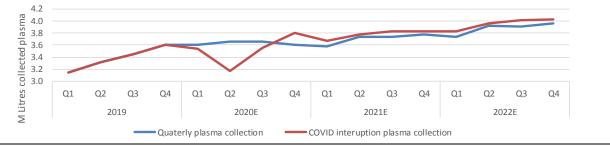
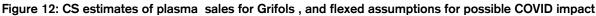
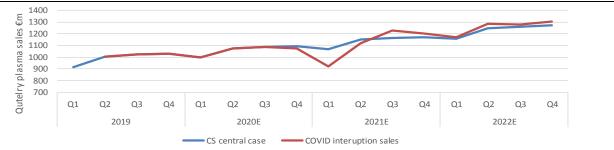


Figure 11: CS estimates of collection volumes of plasma for Grifols , and flexed assumptions for possible COVID impact

Source: Company data, Credit Suisse estimates





Source: Company data, Credit Suisse estimates

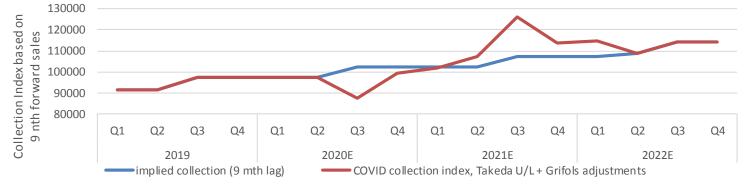


Takeda sensitivity: EPS -2% FY21, +2% FY22

For this sensitivity exercise we replicated the change in assumed growth in collection volumes we have applied to Grifols to Takeda. We have based this on the same calendar quarters and then adjusted to show the relevant quarters that are within the March year end for Takeda. We do not have the same granularity of centre numbers and donation volumes we have with Grifols and so we have simplified the analysis. We have derived an implied collection volume with a 9 month lag based on current and projected plasma sales. We have then adjusted this base line index of volume by the same adjustment factors we have used for Grifols, excluding the Cal 1020 adjustment for Germany, as we assume the majority of Takeda collection from the US where we see only a limited 10 sales impact. Given that plasma products only accounts for a 70% contribution on sales is small. However cash flow could be an important factor to consider. Takeda must manage the situation well in order to gain credibility. There is also a greater capture of both short term negative and mid-term positives within one fiscal year for Takeda.

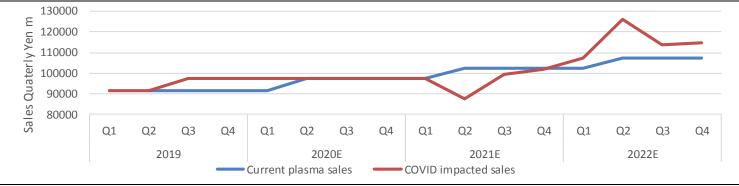
In our CSL analysis we have flexed both donations per centre and center numbers separately. We have not done this for Takeda, and yet for Takeda increased centre numbers are implicit in our underlying growth expectations as their recent expansion has lagged peers.

Figure 13: CS estimates of collection volumes of plasma for Takeda , and flexed assumptions for possible COVID impact



Source: Company data, Calendar year data Credit Suisse estimates

Figure 14: CS estimates of plasma product sales for Takeda , and flexed assumptions for possible COVID impact



Source: Company data, Calendar year data Credit Suisse estimates



Progress on COVID-19 Plasma therapeutics

In our recently published COVID-19 therapeutics <u>tear sheet</u>, we introduced the concepts of both regular plasma and convalescent plasma (from recovered COVID-19 patients) as potential treatment options to help boost immune systems in sick patients. Recall, plasma is the yellow liquid component of your blood once you filter out red blood cells, white blood cells and platelets. Plasma derived products, such as intravenous/subcutaneous immunoglobulin (IVIG/SCIG) are frequently used to help boost immunity in immune deficient patients, and so will likely to be used to help patients recover from COVID-19.

Beyond the standard IG, companies that specialize in plasma derived therapeutics are also developing hyper immune immunoglobulin (H-IG, fractionated plasma with large titres of COVID-19 antibodies) and convalescent plasma (whole plasma taken from patients who have recovered from COVID-19). Both of these therapies require plasma donations from recovered COVID-19 patients. According to data from John Hopkins university, there are c330,000 individuals that have recovered from COVID-19 around the globe (as of April 9th), with the largest proportion of these residing in China.

We understand at this time, collection of plasma from these recovered patients has begun around the world, pre-dominantly in the hospital setting. We expect collection will soon roll out to the plasma collection centres, particularly in the US, as the flow of eligible donors increases and formal collection protocols (testing etc.) are put in place.

Hyper-immune Immunoglobulin (H-IG)

Hyper-immune immunoglobulin is concentrated fractionized plasma product derived from plasma donations from donors that have recovered from the COVID-19 virus. The end product has a high titre of COVID-19 antibodies and will require clinical trials before use. To create it, we estimate c75 patients worth of plasma will produce enough for a 5 day treatment for c 3-4 patients. We understand that lower volumes of plasma from these donors is required (c500ml vs an 800ml average donation).

- Grifols & FDA collaboration. Grifols is also working on an H-IG in collaboration with BARDA and the FDA. We understand that the company is targeting having its product available by July (in 3 months), and may be first to produce the product (with a rapid 6 week production process). Similar to Takeda, collection of plasma has already begun in the US, primarily in the hospital setting. The company may benefit from the collaboration with the FDA and CDC in identifying eligible donors, to speed up development vs peers. Fractionation is expected to take place at Grifol's Clayton (North Carolina) facility, in small batches.
- CSL & Takeda Alliance. This week, the companies announced they are forming an alliance with 4 additional companies (Biotest, BPL, LFB, and Octapharma) to accelerate the development of an unbranded hyperimmune plasma for COVID-19. The alliance is actively encouraging others to join. We understand that Grifols will be contributing its expertise, but will not be a key driving force behind the project due to the simultaneous efforts ongoing in partnership with FDA. No development timelines for this product were shared in the press release. At this stage, the economics for this product in relation to Takeda and CSL remain unknown, but given its unbranded nature, we could expect this therapy could be donated, rather than sold.
- Takeda (TAK-888). Takeda was the first to announce its pre-clinical development for H-IG, TAK-888, an anti COVID polyclonal H-IG but has since terminated sole development. The company stated at its recent investor event that it has begun collecting plasma from patients in Australia and the US and Takeda expects it will take between 9 and 18 months to complete clinical studies. However following the announcement of the CSL alliance, Takeda is re-focusing its efforts away from TAK-888 and on to developing an unbranded product.



Convalescent plasma

Convalescent plasma is where the whole plasma taken from a recovered patient is infused into the sick patients, with filtering but limited processing. Given this, processing time is typically faster versus H-IG and smaller volumes of plasma are required for treatment (we understand donations from two separate donors is sufficient to treat 1 patient). The FDA has also <u>authorised</u> the emergency use of convalescent plasma in the US, so physicians today are able to gain emergency IND to administer convalescent plasma for specific patients. We have already seen anecdotal evidence of this approach being used, first in China and more recently in the US, with success but in very small patient numbers.

- Collection limited to hospital setting. No centres we spoke to during our research on CSL, Grifols and Takeda stated they were ready to take collections from COVID-19 survivors at their respective collection centres. The FDA has announced it is working on master protocols for collection in partnership with NIH and CDC, which we expect will be available imminently. We also note AABB (a non-profit agency focused on transfusion medicine) put out new <u>guidelines</u> on convalescent plasma last week. We expect the publication of these protocol/guidelines will accelerate collection and help advance it away from hospitals and into local collection centres. Increased availability of COVID-19 testing will also help speed up this process.
- Grifols & FDA collaboration. In addition to developing a hyperimmune product, Grifols is also providing resources for the production of convalescent plasma, as part of its agreement with the FDA. We understand the company is targeting to have plasma available to treat patients as early as the end of April (2-3 weeks time). We would not expect this plasma product to be studied in clinical trials given the FDA energy authorization, but may be used to help treat patients in interim period before its H-IG product becomes available.
- We believe that Grifols is particularly well positioned here with a dedicated fractionation facility available (certified for this sort of use during the Ebola crisis).
- Academic alliances also forming for convalescent plasma. We highlight a new selforganised US National COVID-19 convalescent plasma project (link) has recently formed. The group consists of physicians from 34 institutions in 17 states who are investigating use of convalescent plasma, without apparent industry partnerships. The group is providing trial protocols and guidance for healthcare providers looking to utilize convalescent plasma, as well as encouraging plasma donations at local blood banks and the Red Cross.



Appendix

Figure 15: CSL Plasma centre locations



Source: FDA, Company data, Credit Suisse estimates





Figure 16: Grifols plasma centre locations

Source: FDA, Company data, Credit Suisse estimates





Figure 17: Takeda plasma centre locations

Source: FDA, Company data, Credit Suisse estimates



Companies Mentioned (Price as of 09-Apr-2020) Biotest (BIOG.DE, \in 22.8) CSL Ltd (CSL.AX, A\$329.0) China Biologic Products, Inc. (CBPO.OQ, \$106.7) Grifols (GRLS.MC, \in 29.49) Takeda Pharmaceutical (4502.T, ¥3,480)

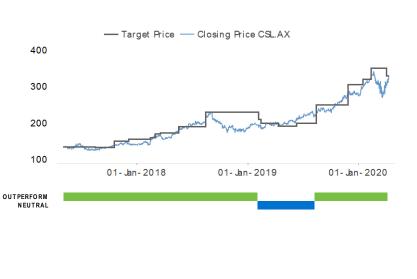
Disclosure Appendix

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3-Year Price and Rating History for CSL Ltd (CSL.AX)

CSL.AX	Closing Price	Target Price	
Date	(A\$)	(A\$)	Rating
05-May-17	133.62	134.00	0
16-Aug-17	125.27	133.00	
18-Oct-17	141.45	150.00	
04-Dec-17	145.31	155.00	*
14-Feb-18	149.29	160.00	
02-Mar-18	160.05	170.00	
19-Mar-18	166.59	173.00	
18-May-18	182.95	190.00	
15-Aug-18	214.58	230.00	
05-Feb-19	193.03	210.00	Ν
13-Feb-19	186.09	200.00	
12-Apr-19	197.86	192.00	
11-Jun-19	212.50	199.00	
14-Aug-19	234.00	249.00	0
28-Nov-19	282.99	305.00	
15-Jan-20	297.74	320.00	
12-Feb-20	328.25	350.00	
03-Apr-20	304.11	329.00	



3-Year Price and Rating History for China Biologic Products, Inc. (CBPO.OQ)

CBP0.0Q	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
06-Jul-17	102.78	129.00	0
28-Jul-17	98.42	123.00	
31-Oct-17	77.71	100.00	*
06-Aug-18	94.86	100.00	Ν
07-Mar-19	83.61	88.00	
13-Mar-20	114.78	115.00	*

* Asterisk signifies initiation or assumption of coverage.





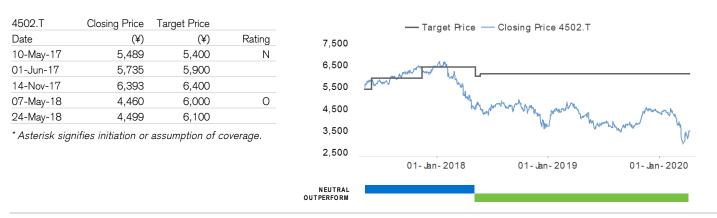
3-Year Price and Rating History for Grifols (GRLS.MC)

GRLS.MC	Closing Price	Target Price	
Date	(€)	(€)	Rating
08-Dec-17	24.08	26.00	N *
02-Aug-19	28.92	27.00	
16-Jan-20	31.89	32.00	

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3-Year Price and Rating History for Takeda Pharmaceutical (4502.T)



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