WILSONS

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Theme
Best Ideas

Sector
Healthcare

Healthcare in 2023: Our Top Six

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We round out 2022 with our annual holiday send-off in which we highlight our top six coverage picks for next year which will see us return enthusiastically from the break. Those stocks are: CSL, Pro Medicus, Clinuvel Pharmaceuticals, Aroa Biosurgery, Immutep and Clarity Pharmaceuticals. There is a clear density of biopharma names (IMM, CU6, CUV, CSL) with critical trial and/or regulatory approval readouts in 2023 which will be pivotal for share price momentum. Separately, stocks which have performed relatively strongly through a tough period (PME, ARX) are now primed to be rewarded as equity market appetites return.

Our Top Picks

CSL (CSL)

Plasma-derived therapeutic protein sales set consecutive records in the Jun-22 and Sep-22 quarters. In volume terms the industry is within 10% of recapturing the growth outlook investors had in mind pre-pandemic. In 2023 we expect market share gains in IG (notably in CIDP). From the pipeline: the HEMGENIX launch in Haemophilia B; the release of garadacimab Phase III results in HAE; and, the final readout from CSL's cardiovascular blockbuster CSL112.

Pro Medicus (PME)

Pro Medicus are heading into 2023 with the largest forward-looking contract revenue pipeline in the company's history, with a growing customer base, particularly in the IDTF/IDN market which service approx. half of the US radiology scan volume. Importantly PME will also expand into new adjacencies with cardiology earnings hitting in 2023. Industry tailwinds are stronger than ever with consolidation spikes, high demand and large cloud shifts by EHR vendors propelling PME's relevance and dominance in US hospitals.

Clinuvel Pharmaceuticals (CUV)

Clinuvel's earning diversification and growth ramps up in 2023, as we expect to see first OTC revenues, key vitiligo and XP trial readouts, and timeline clarity on ACTH launch into the US. Sentiment regarding the first potential competitor drug in EPP has plagued the stock for ~12months awaiting a key Phase III readout – this is more than accommodated for in consensus modelling now justifying its removal as a negative catalyst. Delivery of growth objectives, alongside core business performance should see the stock re-rate over 2023.

Aroa Biosurgery (ARX)

With breakeven point now upon Aroa, 2023 should see the stock re-rate in line with other high growth woundcare stocks with fair value at 7.0-9.0x CY23 EV/Revenue. Aroa's next 12 months will be supported by MYRIAD growth, currently tracking above expectations (>triple in FY23), the launch of SYMPHONY in outpatient centres, leveraging existing relationships with a product ~5x the value and pending approval of their first ENIVO iteration (1Q CY23), opening the door to another US$1B market.

Immutep (IMM)

Immutep makes the list again in 2023 as a top pick. Across 2022, LAG-3 was validated as the third key IO target with BMY's relatlimab approval, IMM met their primary endpoint in Phase II TACTI-002 trial signalling a 2023 registration level study; and importantly, stimulated KOL and pharma interest through two plenary platforms (ASCO, SITC). The first interim data from their (potentially) pivotal TACTI-003 trial in 1L HNSCC is an inflection point as it will showcase the first registration level RCT data of Efti + Keytruda head-to-head with SoC.

Clarity Pharmaceuticals (CU6)

Clarity's 2023 is a transformational year for their business. With the imminent release of their SAR-bisPSMA which presents as a significant de-risking event, Clarity are set for a further four key trial readouts across their portfolio in the coming year. This will allow Clarity to validate the wide utility of copper and their patented technology, and, move into the pivotal trial stage (x3) in 2023, where the propensity for big Pharma intervention elevates markedly in our view.

Featured stocks		
CSL (CSL)	**PT $330.75**	**OVERWEIGHT**
	Revenue ($B)	EV/EBITDA (x)
FY23E	12.7	25.1
FY24E	14.3	20.2
FY25E	15.2	18.3
Pro Medicus (PME)	**PT $71.00**	**OVERWEIGHT**
	Revenue ($M)	EV/EBITDA (x)
FY23E	125.3	67.4
FY24E	152.1	55.2
FY25E	186.0	44.7
Clinuvel Pharmaceuticals (CUV)	**PT $23.53**	**OVERWEIGHT**
	Revenue ($M)	EV/EBITDA (x)
FY23E	85.1	19.1
FY24E	103.8	14.2
FY25E	124.1	11.2
Aroa Biosurgery (ARX)	**PT $1.73**	**OVERWEIGHT**
	Revenue ($M)	EV/Revenue (x)
FY23E	62.4	5.6
FY24E	78.6	4.4
FY25E	98.3	3.5
Immutep (IMM)	**PT $0.91**	**OVERWEIGHT**
	Revenue ($M)	EBITDA ($M)
FY23E	120.0	86.1
FY24E	0.0	(36.0)
FY25E	0.0	(21.2)
Clarity Pharmaceuticals (CU6)	**PT $1.22**	**OVERWEIGHT**
	Revenue ($M)	EBITDA ($M)
FY23E	0.0	(23.9)
FY24E	0.0	(26.5)
FY25E	0.2	(44.5)

Wilsons' Healthcare coverage overview

Figure 1: Current Healthcare coverage universe across Biopharma, Medical Device, Healthcare Services and HealthTech

Company Name	Ticker	Mkt cap ($M)	EV/EBITDA			EV/Revenue				
			FY23E	FY24E	FY25E	FY23E	FY24E	FY25E	Rec	PT
Biopharmaceutical										
CSL Ltd	CSL.AX	145,046	22.2x	17.9x	16.3x	7.6x	6.7x	6.3x	O	330.75
Telix Pharmaceuticals Ltd	TLX.AX	2,230		59.6x	19.7x	8.1x	6.5x	5.2x	O	8.40
Clinuvel Pharmaceuticals Ltd	CUV.AX	1,029	20.6x	15.9x	13.1x	10.7x	8.7x	7.3x	O	23.53
Mayne Pharma Group Ltd	MYX.AX	348	-7.3x	-25.9x	2815.4x	2.7x	1.8x	1.6x	U	0.17
Opthea Ltd	OPT.AX	453							O	1.50
Immutep Ltd	IMM.AX	312							O	0.91
Clarity Pharmaceuticals Ltd	CU6.AX	248							O	1.22
Antisense Therapeutics Ltd	ANP.AX	58							O	0.36
Medical device										
Resmed Inc	RMD.AX	61,817	31.7x	28.6x	26.8x	10.3x	9.4x	8.7x	O	38.24
Cochlear Ltd	COH.AX	13,940	27.8x	23.4x	21.1x	7.4x	6.6x	6.0x	O	245.00
Fisher & Paykel Healthcare Corporation Ltd	FPH.AX	12,994	41.8x	33.7x	29.8x	10.0x	9.0x	8.3x	MW	20.00
Polynovo Ltd	PNV.AX	1,314	402.0x	153.6x	66.6x	20.7x	16.5x	12.6x	U	1.20
Nanosonics Ltd	NAN.AX	1,456	96.8x	72.7x	52.2x	8.7x	7.9x	7.0x	O	5.50
Aroa Biosurgery Ltd	ARX.AX	377		66.6x	25.6x	6.6x	5.0x	4.0x	O	1.73
AVITA Medical Inc	AVH.AX	263			28.3x	2.8x	2.2x	2.0x	MW	1.88
ImpediMed Ltd	IPD.AX	162			31.5x	7.6x	4.6x	2.4x	O	0.30
Next Science Ltd	NXS.AX	139		21.7x	6.0x	3.9x	2.6x	1.7x	O	1.80
EBR Systems Inc	EBR.AX	115							O	1.50
Somnomed Ltd	SOM.AX	113	56.9x	8.9x	7.2x	1.2x	1.1x	1.0x	O	2.40
Oncosil Medical Ltd	OSL.AX	45				21.6x	6.9x	2.4x	MW	0.06
Cleanspace Holdings Ltd	CSX.AX	32				0.7x	0.6x	0.4x	MW	0.71
Healthcare services										
Ramsay Health Care Ltd	RHC.AX	15,193	10.0x	8.3x	7.5x	1.4x	1.3x	1.2x	O	69.31
Integral Diagnostics Ltd	IDX.AX	629	8.5x	7.2x	6.6x	1.8x	1.6x	1.6x	MW	2.80
Capitol Health Ltd	CAJ.AX	340	6.9x	6.2x	6.1x	1.6x	1.4x	1.4x	O	0.42
Pacific Smiles Group Ltd	PSQ.AX	255	10.8x	8.2x	6.8x	1.5x	1.3x	1.1x	MW	1.65
Silk Laser Australia Ltd	SLA.AX	105	4.7x	4.2x	3.9x	1.2x	1.1x	1.0x	O	3.62
HealthTech										
Pro Medicus Ltd	PME.AX	6,301	68.9x	56.7x	46.3x	49.8x	41.0x	33.5x	O	71.00

Source: Refinitiv, Wilsons.

CSL Limited (CSL)

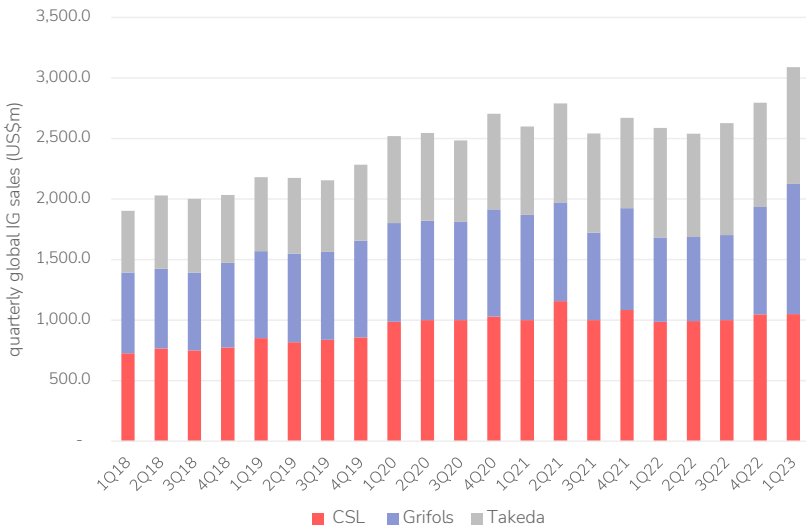
OVERWEIGHT

Pivotal trial readouts and drug launches, coupled with margin restoration

Global IG supply fully recovers in 2023. Sep-Q set another industry record for IG sales at US$3.1B IG (HIZENTRA). We assess that IG sales in dollar terms are within 5% of where the market predicted them to reach before the pandemic hit (modelling forward global demand growth of 8%) **(Figure 2)**. In gram terms, the industry is tracking at 90% of predicted demand. In other words, 2023 should operate as though the pandemic never happened from a volume/revenue perspective. Incremental IG sales in FY23-24e for CSL Behring are US$350M and US$800M, respectively. Gross margins may stay structurally lower but this favours CSL and Takeda, both of whom have higher margin offsets through Specialty and Rare Disease product portfolios.

CSL gunning for Grifols in neurology (CIDP). With Grifols structurally less profitable, their large CIDP GAMUNEX-C franchise is vulnerable. CSL and Takeda are both coming for Grifols in neurology with HIZENTRA and HYQVIA, respectively. We are picking HIZENTRA to win market share on the basis of its Medicare Part B coverage status and expanded FDA indication for flexible dosing in the home setting. We assess US$100M incremental gross profit for every 5% of this market CSL takes, attended by a mix-shift towards at-home subcutaneous therapy. Read our latest CIDP market and competitive review here.

Figure 2: Estimated quarterly IG sales 2018-23e (CSL, Grifols and Takeda).



Source: CSL, Grifols, Takeda, Wilsons.

Extending dominance in Haemophilia B. HEMGENIX is commercially available in the USA from November as the first and only FDA approved gene therapy for Haemophilia B. This asset holds value in its ability to expand and fortify CSL's leadership position in Haemophilia B, already established with IDELVION. The potential to replace ≥10 years of regular prophylactic management with a single shot of HEMGENIX is a powerful prescribing option for adolescent, young adult or other patient subgroups for whom compliance with routine prophylaxis is problematic. Whilst HEMGENIX may cannibalise prophylaxis options including IDELVION, the lesser long(*ish*)-acting BENEFIX (Pfizer), ALPROLIX (Sanofi) and REFIXIA (Novo) are likely to be 'eaten' first. Any IDELVION patient switched to HEMGENIX brings higher gross profit dollars with them. HEMGENIX grows the Haemophilia B market by at least 10% with all of that exclusively CSL's. See an analysis of the Hemgenix opportunity here.

Garadacimab can upset Takeda in hereditary angioedema (HAE). The August announcement that the Phase III VANGAURD trial had met its endpoints gave nothing away on efficacy metrics. We infer that the results are probably stunning; CSL choosing to maximise their impact by allowing the peer review process to run its course prior to publication in appropriate journals (Phase II made *The Lancet* this year). As a reminder, in Phase II garadacimab was associated with a 99% reduction in HAE attacks[1] which compares favourably with TAKHZYRO (>90%)[2] and ORLADEYO (44%)[3]. We estimate global sales of US$1.7B over the last 12 months for HAE prophylaxis. The market is growing at 20% per annum as diagnosis rates improve and clinical practice transitions from treating episodic attacks to routine prophylaxis. We estimate peak sales for garadacimab at >US$500M noting that HAEGARDA peaked at ~US$400M before the launch of TAKHZYRO.

Vifor Pharma's first 12 months. Our bigger picture take on the Vifor acquisition as a platform to operationalise CSL's cardiorenal R&D pipeline takes a backseat as we weigh immediate performance. FY23e forecasts look for a continuation of iron replacement growth, the launch of KORSUVA and a rebound in dialysis demand over 2023.

Valuation. Our $330.75/sh SOTP DCF valuation disaggregates to $268.75/sh (US$180/sh or 22.6x EV/EBITDA at spot AUD/USD) for base earnings + $62/share for CSL R&D pipeline (HEMGENIX sales execution, garadacimab approvals, CSL112 Phase III success, clazakizumab Phase III success). At this stage we have not conducted formal valuation analysis for Vifor R&D assets including KORSUVA, sparsentan, vamifeport, INS-3001 and SNF-472.

[1] Craig, T., *et al.* (2022) Prophylactic use of an anti-activated factor XII monoclonal antibody, garadacimab, for patients with C1-esterase inhibitor-deficient hereditary angioedema: a randomised, double-blind, placebo-controlled, phase 2 trial Lancet 399: 945-55.
[2] Benerji, A., *et al.* (2018) HELP Investigators. Effect of Lanadelumab compared with placebo on prevention of hereditary angioedema attacks: a randomized clinical trial. JAMA 320(20):2108–2121
[3] Zuraw, B., *et al.* (2021) Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: a randomized, double-blind, placebo-controlled phase 3 trial. J Allergy Clin Immunol 2021;148(01):164–172.e9

Pro Medicus (PME)

OVERWEIGHT

US industry backdrop is stronger than ever, supporting Visage's path to dominance

First cardiology revenues in CY23. PME's expansion of their Visage offering into new clinical adjacencies is coming to fruition with their cardiology viewer, which has been in beta-testing over the past year, looking to generate first revenues in 2023. This has been a long time coming, with many on both the investor and customer side waiting for expansion outside of radiology for years that has been yet to surface. There are scarce areas to criticize Pro Medicus however this has been one area in which they have overpromised and underdelivered in terms of time to execution. It is happy to see management committing to first revenues in CY23 bringing this long-awaited adjacency expansion into reality. As a reminder, we have previously assessed an expansion of Visage's current US TAM (in radiology) by ≥25% (~$400M) with a cardiology specific viewer product, assessing an opportunity for a Visage based platform to take ~23% total US cardiology imaging market share by FY40e.

M&A beckoning given balance sheet strength; a focus on adjacency expansion. We forecast net cash for PME of ~$90M as of end FY23e. They continue to pay a dividend (50% payout ratio), and are engaged in a share buyback (active in 2H FY22). Investor focus continues to ponder the use of these 'leftover' funds and optimisation of their capital structure. PME note they have maintained this level of cash for "strategic flexibility" purposes. The ability for PME to acquire small businesses that add significant product or R&D firepower/knowledge that can be leveraged by the Visage 7 platform is desirable – with a key focus being on advancing their development progress into new adjacencies, akin to what they are now doing with Cardiology. We have previously assessed ophthalmology and neurology as key expansion areas where acquisition of novel software products or R&D teams knowledgeable in the space could markedly bring forward new product expansion timelines.

Cloud adoption tailwinds in US intensify. The US healthcare system will see the greatest transition to cloud infrastructure in the next two years than it has ever seen before with both EPIC and Cerner EHR platforms all moving to the cloud in 2023. In our view this markedly accelerates the pace and likelihood at which new US healthcare customers may look to transition to cloud-based enterprise imaging/PACS solutions, of which Pro Medicus' Visage offering is leading. Overhauling hospital IT infrastructure solely to accommodate a cloud-based radiology product is fairly unlikely, and yet despite this PME has seen consistent contract wins for their cloud-based Visage offering. We view the 'forced' movement of hospitals to cloud for their EHR systems as a driving force of imaging/PACS product revisions and cloud transitions – and thus Visage cloudPACS contract wins.

US industry readthroughs suggest above modelled organic volume growth for radiology imaging and pivots in business model to satisfy demand. RadNet's (NASDAQ:RDNT) 3Q22 results were a useful readthrough for US radiology imaging volumes and conditions, given the size and scale of RadNet's reach in the US market. Key result takeaways include: a) COVID procedure impacts to scan volumes have abated, with scan volume CAGR tracking ahead of pre-pandemic levels; b) RadNet, a roll-up business, are adopting a hybrid greenfield strategy to service the underlying demand that cannot be met, particularly in regional areas; c) staffing shortages are the major impediment to marked scan volume growth at present, but are easing MoM; d) consolidation within the radiology industry continues to be strong, and is accelerating as many businesses that folded during the pandemic are being acquired by larger consolidators (such as RadNet); and e) utilisation of higher modality imaging (CT, MRI, PET) continues to outpace baseline scan volume growth (2x) driving larger file size storage and processing requirements. All of these readthroughs are positive for PME, with their Visage 7 product and contract structure optimised to make the most of these tailwinds (volume growth, higher modality skew, network consolidation).

Consolidation thematic accelerates. As we have discussed before, US Healthcare consolidation is a key tailwind for PME and one that continues to intensify as we move to the end of the pandemic. Latest US hospital M&A data shows that; a) deals are returning from peak pandemic impacts in terms of number; b) average deal value continues to grow; and c) the absolute quantum of M&A spend is increasing year on year in the US market. All are supportive of PME's top-down Visage customer target strategy.

Independent reporting ranks PME's Visage 7 product on top. The latest KLAS 2022 report ranked Visage 7 as #1 of the Universal imaging viewers alongside key legacy incumbents (i.e. AGFA, GE Healthcare, Philips) as well as newer competitors (i.e. Mach 7). Across key metrics including product performance, support and overall satisfaction we drew insights from the "Likelihood to Recommend" and "Would you buy again" categories, clearly showing strong stickiness of existing Visage customers (100% buy again, 8.5/9 recommendation score), and waning loyalty of customers to legacy systems (41.4% buy again for GE, 4.9/9 recommendation score). These industry feedback points continue to support our thesis that legacy players such as GE continue to lose market share, have no competitive levers to win it back, and may actively seek acquisition of technology such as Visage 7 as their way back into this market – particularly given the oncoming cloud wave with no product/s to support it.

Valuation. Our SOTP $71/share PT is premised on an M&A DCF assessment reflecting approx. $61/sh for core business (Visage 7/RIS) and $10/sh for cardiology expansion, with our PT reflecting a synergy premium to our fundamental SOTP DCF valuation ($49.75/share). Acquisition attractiveness remains high in our view.

Please see our latest PME research report here.

Clinuvel Pharmaceuticals (CUV)

OVERWEIGHT

Diversification in full swing

Negative catalyst built into share price. Phase III trial results from SCENESSE's first potential competitor in the EPP indication, Dersimelagon, are imminent, following study completion on August 5th this year. Given Dersimelagon's is mechanistically similar to SCENESSE, as a melanocortin receptor agonist (albeit delivered as a once-a-day oral formulation) we have no reason to believe the results will be anything but positive and, expect Mitsubishi Tanabe will target a CY24 launch. Anticipation of these results however, has plagued the CUV share price and sentiment for the last ~12 months. Our modelling of SCENESSE in EPP has always accounted for other market entrants (including Dersimelagon), with SCENESSE peak market penetration remaining at ~35%. In our view, ours and consensus modelling, and current share price (-32% YTD) now more than account for the controversy surrounding a second EPP market entrant (within 12 months) and with that, should warrant removal as a negative catalyst in investors' minds. Further, we anticipate feedback in 2023 regarding CUV's label application to expand to include adolescent populations for SCENESSE management of EPP broadening the TAM – akin to the Dersimelagon Phase III trial (aged 12 and over).

Vitiligo trial readouts with monotherapy approach imminent. In October, CUV announced that the first patient had been enrolled in their newly initiated CUV104 study of SCENESSE in vitiligo. Whilst the indication expansion of SCENESSE into vitiligo had been on pause for some time (~5 years), the company now benefits from two de-risking factors. First, there is a clearer path to market in the US paved by Incyte with their Opzelura (ruxolitinib) approval in July (given prior there were no predicate approvals in this indication). Second, CUV are pursuing two parallel programs in vitiligo, one with SCENESSE monotherapy (CUV104), and one in combination with NB-UVB (CUV105) – allowing Clinuvel optionality to take the best, most-effective approach forward. Therefore, CUV104's trial results expected in 2H CY23, represent a key milestone for CUV. Clinuvel have also put a timeline on Vitiligo sNDA FDA submission – being 30 months from Nov 2022. We see the opportunity for SCENESSE in vitiligo as the largest pipeline opportunity (>$1B TAM) and assess SCENESSE as differentiated in its systemic approach- addressing a portion of the vitiligo patient segment that is most underserved and desperate for effective therapies, where current treatments (including those seeking regulatory approvals at present) are inadequate.

Progress update on ACTH dossier submissions and plan in 2023. As a reminder, the ACTH opportunity for CUV is somewhat opportunistic, in that the current US market has been dominated by a single ACTH product (Acthar gel) marketed by Mallinckrodt Pharmaceuticals for over a decade, who are in bankruptcy court owing to their involvement in the US opioid scandal. Recently (Jan 2022) a second market entrant emerged in ANI Pharmaceuticals with a similar ACTH gel product, with a notable label omission for Infantile Spasms. At ANI's 2Q22 result in August they raised revenue guidance for 2022 to US$40-45M (from US$35- 40M) in their first year of launch, noting significant clinical uptake and traction. 3Q22 results last month from ANI and Mallinckrodt reported net revenues of ACTH products of US$12.6M and US$125.7M for the quarter, respectively (supporting a >US$500M/year ACTH market). Clinuvel, having found a clinical grade GMP ACTH manufacturer, are currently completing validation testing for a Drug Master File (DMF) submission to the FDA for NEURACTHEL (expected 2023). ACTH is a generic product having been used for >50 years for a range of approved indications. We view the opportunity for Clinuvel as being a 3rd market entrant sharing a piece of the current >US$500M ACTH pie, across select indications with the most clinical evidence and highest unmet need- Infantile Spasms and Relapsing Multiple Sclerosis. These two indications in the US market could support an incremental potential peak US$290M (A$400M) NEURACTHEL revenue line, which is not accounted for in consensus or our current estimates presenting upside to CUV's current valuation. We expect CUV to provide updates in 1H CY23.

Healthcare Solutions (OTC) launch. In September, CUV provided an update on their OTC business, with their first (of 4) products – CYACELLE – soft launching, with a full launch in 2H23. CYACELLE is a high level, polychromatic, photo-protectant lotion specifically aimed at those audiences with high risk of skin cancer, immunocompromised and audiences with high levels of sun exposure in outdoor endeavours (underserved populations). CUV have outlined a 35M consumer target market audience (with 4% annual growth potential). We view the 4th product line (M2) focused on restabilising pigmentation (aka tanning) as the most interesting – which is anticipated to launch toward end 2023/early 2024. The current sunless tanning market is estimated at US$1.4B per year with the lion share of this spend on lotion/topical products. The ability for CUV to leverage their melanocortin know-how to deliver a non-pharmaceutical, topical, safe, tanning agent that would protect from UV damage is an incredibly appealing opportunity and would find a clear and sizeable market within the luxury dermo-cosmetics segment globally. Our current consumer OTC product forecasts are conservative which assume a premium priced product (average ASP of ~$200/bottle, high gross margin) with modest revenue contribution in FY23-24E ($0.1M and $1M respectively). No timelines have been provided regarding the remaining product lines but may represent upside to current estimates.

Valuation. Our risked $23.53/sh SOTP valuation disaggregates to $15.04 /sh for the EPP and modest OTC opportunities plus $8.50/sh for the pipeline clinical programs (XP, Vitiligo). There is no value attribution for stroke or NEURACTHEL (ACTH) at this point in time, noting we see material valuation upside potential for ACTH pending the opportunity being further clarified in terms of launch timelines. Unrisked valuation is $36.18/sh.

Aroa Biosurgery (ARX)

OVERWEIGHT

Imminent profitability driven by strong sales traction, with pipeline assets to support further gains

Profitability hurdle overcome. Aroa's stock has suffered the same setback as the rest of the non-profitable medical device companies across FY22E, remaining essentially untouchable until the tip into positive earnings territory. Whilst Aroa's profitability was previously scheduled for FY24E, growth run rates in OviTex, through TELA's growing position in hernia (~3% penetrated), rapid uptake of the MYRIAD product suite in trauma-related operations and a substantive Fx tailwind across the rest of the year (NZ$5-9M in total), mean Aroa's breakeven point will be met by FY23E with positive EBITDA cash flow from there-on out (following a small positive EBITDA at 1H23). With profitability therefore expected in the near-term, we expect this to be the catalyst for Aroa's valuation re-rate to be in line with an 8.0x normalised CY23 EV/Revenue multiples afforded to other woundcare growth stocks backed by IP and niche, less-competitive markets (Vericel, Establishment Labs).

MYRIAD finds its feet with major market share gains to be had. In 1H23 the growth in Myriad (+44% vs pcp) also supported a 400bps gross margin increase to 81% (on a constant currency basis), mainly driven by their Myriad Morcells product. The success has spurred Aroa to add a fine powder Morcells product which will look to achieve broader use alongside Myriad Matrix. We see this as particularly savvy, given currently, Aroa's Matrix and Morcells products are used separately, and the combination of the two (with the fine powder retaining the price of the traditional Morcells product) will materially drive up value per case. Aroa's 1H23 results suggest Myriad is tracking ahead of previous guidance (sales to triple in FY23 vs FY22).

SYMPHONY launch. Aroa's SYMPHONY product is also now set to formally launch in April 2023, which will see Aroa position SYMPHONY as a highly efficacious product useful in both the inpatient and outpatient/physician office setting, at a 40% discount to competitors, with pricing for SYMPHONY at ~US$62/cm^2. This however represents ~5x the value of MYRIAD, which will attract >99% gross margins and leverage outpatient centres associated with MYRIAD-using hospitals (requiring minimal further investment into the US sales force). Whilst changes to CMS coding expected next year (now pushed out to CY24) may have allowed rapid uptake in the physician office setting (separate to the outpatient setting) we still assess upside in this setting in CY24 which will be supported by further clinical evidence releases. After recently completing their 10-patient pilot study, Aroa have now commenced a follow-on randomised control trial (RCT) enrolling 120 patients across a number of sites in the US assessing SYMPHONY vs. current SoC.

ENVIO launch next year with material revenue from FY24E. Aroa's newest product - their deadspace management platform, ENIVO was submitted to the FDA on November with regulatory outcome expected in 1Q CY23 (~103-day review process). As a reminder, the ENIVO system employs an external portable vacuum device coupled to a specially designed AROA ECM™ implant device to draw separated tissue surfaces together and remove excess fluids from the surgical site to reduce seromas and ensure proper wound closure. Recent pre-clinical study results demonstrate ENIVO as a significant improvement to current surgical drain options (in terms of seroma reduction, fluid removal and wound closure). Aroa plan to commence their pilot clinical trial which will assess the use of ENIVO is mastectomy patients in 1H CY23.

ENIVO market opportunity. Without any exact predicate devices, we look to the US drain market for assessment of ENIVO's market opportunity. In the US, there are ~3M suction drains (SOC) used per year with 2 drains used per patient on average (~1.5M cases). Approximately half of these patients (750K) are considered high-risk which currently, often results in taking drains home. We see Aroa's initial target market within the ~210K patients (SAM) within the plastics & reconstructive market, where they will leverage their relationships established with both the OviTex and MYRIAD product lines. This will allow Aroa to cross-sell their growing product pipeline without large increases in the US direct sales force (currently at 35 personnel). We estimate an ASP of US$2.5K, which is likely to be included in the overall costs of the surgery, generating a potential US$200M in revenue (at 25% market penetration) in this indication alone. At this stage we incorporate no revenue for ENIVO in our model until >FY26E, which pending FDA approval in 1Q CY23, could represent material upside to our FY24-FY25E forecast.

Figure 3: TAM breakdown for ENIVO

Breast reco./Abdominoplasty US cases/year	600K[4]
SAM (high-risk)	300K
ASP per device	~US$2.5K
Immediate TAM	US$750M
Assumed penetration	25%
Peak sales/year	US$200M

Source: as referenced, Aroa, Wilsons estimates,

Valuation. Our PT of A$1.73 per share represents an 8.0x a normalised CY23 EV/Revenue multiple (to align with ASX and International peers given disparate year ends). This PT demonstrates a premium to the international median of 3.6x CY23 EV/Revenue but is set at a discount to our fundamental DCF valuation of A$2.34/share owing to market cap and liquidity discounts. The multiple is justified given it is in-line with international woundcare comps (Vericel at 9.0x, Establishment Lab Holdings at 7.6x), which akin to Aroa are backed by their own IP as well as niche markets, with less competitive intensity.

Please see our latest ARX research report here.

[4]2021 ASAPS Plastic Surgery Statistics

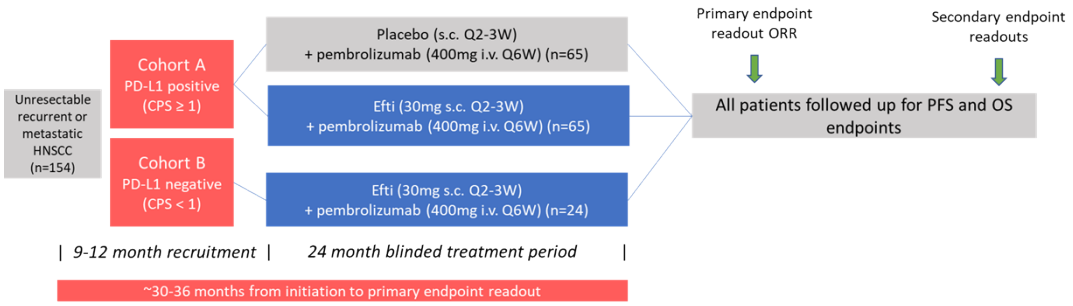
Immutep (IMM)

OVERWEIGHT

TACTI programs the linchpin to strategic investment

TACTI-003 first data readout. In 1H CY23 we will see the first readout from IMM's potentially pivotal Phase IIb study in 1st line HNSCC evaluating Efti in combination with blockbuster anti-PD-1, Keytruda. This is a key inflection point as it may be the first study with this IO-IO combo to demonstrate Efti efficacy head to head in a registrational level RCT, remembering that the 2nd line data in HNSCC patients from the TACTI-002 study was adequate to gain Fast Track Designation from the FDA, and support movement straight into a 'pivotal' Phase IIb in a higher line of therapy. We assess this first readout may be a major de-risking point for strategic partners, noting of course that more mature data in 2H CY23 is also important. The first patient was enrolled in TACTI-003 in August 2021. The recent trial in progress presentation at SITC (November) highlighted that they have recruited 53 of the 154 patients thus far.

Figure 4: TACTI-003 trial design overview



Source: Immutep, Wilsons.

Phase III NSCLC program to be revealed. On the back off their successful Phase II TACTI-002 trial readout, Immutep are in discussions with regulators (including FDA) regarding registrational trial design in 1L NSCLC with an Efti plus Keytruda combination (potentially also including adjunct chemotherapy). We will get confirmation of trial design in 1H CY23 with first patient enrolment noted as being in 2H CY23. Immutep have discussed an adaptive Phase II/III trial design is being explored with carries with it benefits including: a) the ability to progress both established Efti + Keytruda combo in RCT design as well as the earlier triple combo (Efti + Keytruda + chemotherapy) in parallel; b) potential interim readouts, that guide continued trial progression as well as support investor momentum; and c) lower potential R&D expense as adaptive studies often require fewer participants and can be conducted in shorter timeframes than some traditional parallel arm RCTs. Taking this approach, the early INSIGHT-003 data (recent triple combo study) may be able to inform the final SoC comparator arms despite it being less validated on the efficacy front at present. Initial comments from IMM suggest overall survival (OS) as a potential primary endpoint and a focus on TPS ≥1% PD-L1 subgroups only (in line with their recent Fast Track Designation) optimising success likelihood. Confirmation of the trial design, and importantly the associated budget required are keenly awaited by the market. As of end Sept, IMM had $74M net cash. A registrational trial budget in 1L NSCLC is challenging without design.

Big pharma validation continues to flow; MSD not the only interested party. One major criticism from investors continues to be how Immutep have cornered themselves with Efti, in the sense that only MSD would be interested in acquiring the asset given its major development programs (TACTI-002/3) are tied to Keytruda combinations. Immutep have just recently (Nov) signed another new Clinical Trial Collaboration Agreement with Pfizer and Merck KGaA to combine their anti-PD-L1 BAVENCIO with Efti. This does two key things; 1) it validates the clinical and potential market benefits of Efti from dominant big pharma with oncology franchises; and 2) it provides a further opportunity to show the "pan anti-PD-1/L1" applicability of Efti. This second point is of course critical to demonstrate to both strategic players, as well as investors, that the value to be unlocked by acquisition of Efti is broad, and extends beyond its demonstrated actions with Keytruda alone and that MSD is not the only ones at the table.

INSIGHT-005 trial kicks off in 2023 – further Efti indication expansion. The new INSIGHT-005 trial will explore the combination of Efti plus anti-PD-L1 BAVENCIO (avelumab – from Pfizer/Merck) in 30 patients with metastatic urothelial carcinoma (UC). First patient dosing is anticipated 1H CY23. This trial builds upon preliminary efficacy data from Immutep's INSIGHT-004 trial with the same combination in varied solid tumours. The prior trial data (albeit from a tiny sample size n=12) showed good efficacy signals with a response rate (ORR) of 41.7% - higher than current IO in a post-chemotherapy/2L setting (anti-PD-1/L1 monotherapy trials – 15-30% range ORR)[5].

Pipeline updates: IMP761 & LAG-3 small molecules. 2023 should uncover more regarding earlier pipeline assets from Immutep; notably their IMP761 LAG-3 agonist which they have just announced has completed manufacturing scale up to 200L that will support its use in IND-enabling studies and first human clinical trials next year. Given the early nature of IMP761's development it is excluded from our risked valuation, however preclinical data supports our interest and excitement in its continued development – particularly with respect to the potential addressable markets (akin to Humira – with 2021 sales of >US$20B).

Valuation. Our $0.91/share risked PT disaggregates to a) Efti NSCLC licensing ($0.53/sh); b) Efti in HR+/HER2- breast cancer ($0.30/share); and c) Efti in HNSCC ($0.09/sh). Our unrisked valuation is $2.50 per share, with a potential >$2B acquisition valuation assessed based on predicate transactions in the oncology sector.

[5] Tassinari E *et al.* (2022) Treatment Options for Metastatic Urothelial Carcinoma after First-Line Chemotherapy. *Cancer Manag Res*. 14: 1945-1960.

Clarity Pharmaceuticals (CU6)

OVERWEIGHT

Key trial readouts supporting Cu proof of concept and pivotal progression

Clarity positioned to enter a Phase III trial in CY23 following pending clinical trial results assessing the diagnostic value of SAR-bisPSMA in prostate cancer. PROPELLER was designed as a multi-centre, blinded review, dose ranging, non-randomised Phase I study to assess the safety and efficacy of 64Cu SAR-bisPSMA in prostate cancer diagnosis. The trial was planned to enrol 30 participants with confirmed prostate cancer (pre-prostatectomy; typically partial removal of the prostate gland). We are confident of positive trial results, given safety is bolstered by sound pre-clinical data and broader SAR-copper use validated in NETs, and released preliminary imaging results from the trial demonstrate efficacy of 64Cu-SAR-bisPSMA compared to 68Ga PSMA-11.

Two SARTATE trial readouts in Neuroblastoma and Neuroendocrine Tumours (NETs) expected in CY23 will further de-risk Clarity's portfolio. These two trial readouts are important for different reasons. Clarity's diagnostic NETs trial - DISCO is expected to be released in 3Q CY23. Similar to SAR-bisPSMA, DISCO will be used to validate copper against the traditional isotopes (^{68}Ga) and demonstrate its utility across a wider variety of indications (which presents lucrative to Big Pharma still wanting a piece of the radiopharma pie). Clarity's Neuroblastoma diagnostic and therapy trial – CL04, however will a) be the first in-human data to validate the utility of ^{64}Cu-SARTATE in Neuroblastoma patients (noting that in-human trials conducted in NETs target the same SSTR2 receptor) and b) represents a pivotal point for Clarity to divulge their plans in either taking the Neuroblastoma diagnostic separately or, creating an appropriate pivotal trial design to see both the diagnostic and therapy, go to market at somewhat similar times. Given this is currently difficult to assess, (as a result of the rarity of the disease and lack of appropriate clinical trials) this would create a significant step-change in revenue timelines and opportunities for Clarity, with therapy anticipated launch year currently at FY27 (and US$123M peak sales by FY30).

Clarity may be eligible for two priority review vouchers worth ~US$100M each. Clarity's position in Neuroblastoma is also strategic in that the two orphan drug designations (ODD) status awarded (one for diagnosis and one for therapy), allow Clarity access to two potential priority review vouchers, with recent voucher sales at ~US$100M. This may allow Clarity to materially increase early revenue generation providing funding for their larger, and more commercial opportunities in PSMA-positive (SAR-bisPSMA) & negative (SAR-Bombesin) prostate cancer therapy.

The real-value of Bombesin. Clarity's execution of their multiple programs has been impressive across CY22. Recently, our timelines for the SAR-BBN diagnostic and therapy programs were brought forward by ~3 years. Our original estimates for SAR-BBN in prostate cancer diagnosis were predicated on the company prioritising other programs (PSMA-positive prostate cancer therapy) and thus were delayed due to capital allocation. Their SAR-BBN diagnostic expected to be on-market by FY26E end (originally FY30E) and their therapy by FY30E end (originally FY32E). The shifts in timeline increase the value of the diagnostic program by 63% and the therapy program by 34%. With their first large scale trial in diagnosis PSMA-negative prostate cancer – SABRE, now expected to be completed in 4Q CY23, 2023 will demonstrate a pivotal point for Clarity to unlock value in this currently untouched market. As a reminder, Clarity's BBBN programs in PSMA-negative prostate cancer and therapy represent their largest, long-term opportunity, with each positive trial readout representing a significant de-risking event.

Radiopharma M&A propensity remains hot. With looming multiple positive clinical trial results as well as a streamlined 'product suite' offered by only two isotopes (^{64}Cu & ^{67}Cu), CY23 appears to be a prime opportunity for Big Pharma to tap into radiopharma. In CY23, players such as Merck and Roche, who have missed out on the radiopharma opportunity, will be able to view Clarity as a de-risked Phase II/III company (which is historically most popular in radiopharma deals) and easily plug in Clarity's assets to join in on the success of the likes of Novartis. As a reminder, in November this year, Lantheus paid $260M upfront for a double bill of licenses for two of POINT Biopharma's ^{177}Lu therapy candidates (for metastatic castrate resistant prostate cancer and NETs), with another $1.8B predicated on FDA approvals. These potential deals are only bolstered by commercial quantities of ^{67}Cu becoming available in early 2023 (manufactured by NorthStar) which will quell any concerns over the large-scale production issues associated with copper.

Valuation. Following the de-risking of the SAR-bisPSMA diagnostic agent with imminent Phase I/II results and re-adjusting timelines for the SAR-Bombesin PSMA-negative prostate cancer diagnostic (by ~3 years), our 12-month PT is lifted to $1.22/sh. Our PT for Clarity is based on a risked SOTP valuation which utilizes real-options DCF for key pipeline programs; a) prostate $1.01/sh; b) NB $0.11/sh; and c) NETs $0.10/sh. No value is attributed to the breast cancer Dx program at present. Unrisked PT is $4.45/share. Clinical readouts in the next 6 months further de-risk our valuation by ~15% to $1.40/sh.

Please see our latest CU6 research report here.

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