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Clinuvel Pharmaceuticals (CUV)

The Bronze Age

Recommendation
Buy (Initiation)
Price
$14.12
Target (12 months)
$24.00

GICS Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**70.0%**
Dividend yield	**0.4%**
Total expected return	**70.3%**

Company Data & Ratios	
Enterprise value	**$548.8m**
Market cap	**$705.6m**
Issued capital	**49.4m**
Free float	**89.1%**
Avg. daily val. (52wk)	**$1.7m**
12 month price range	**$14.25 - $28.72**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	19.20	17.98	18.23
Absolute (%)	-26.46	-21.47	-22.55
Rel market (%)	-20.69	-17.14	-27.19

Scenesse growth, profits expected to continue

Clinuvel (CUV) is one of very few ASX-listed biopharma companies directly commercialising novel pharmaceuticals across the US and EU in a highly profitable manner. Clinuvel distributes Scenesse, the only approved treatment for patients suffering from a rare inherited disease called erythropoietic protoporphyria (EPP).

Sales of Scenesse have grown at a 3-year CAGR of 34% to A$78m in FY23. Clinuvel's direct distribution model has resulted in seven consecutive years of profitability, with an EBIT margin between 52-53% over the last three financial years. With no alternative EPP treatments expected for at least another three years, revenue growth and high margins are expected to continue in the near-term.

Diversification beyond EPP

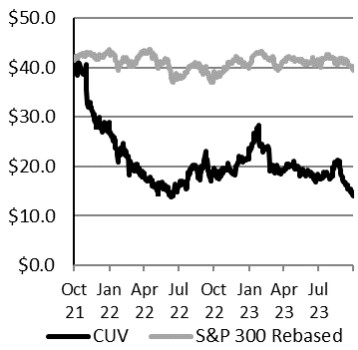
Clinuvel is conducting a range of pharmaceutical R&D activities and new product launches to diversify its commercial opportunities beyond EPP, including: (1) expanding the approved indications of Scenesse, such as in vitiligo, XP, VP and stroke; (2) developing additional melanocortin pharmaceuticals, such as the generic drug Neuracthel; and (3) launching a range of topical 'PhotoCosmetic' consumer products over the next 2-3 years.

Investment view: Initiate with a BUY; PT $24.00

Our valuation is based on a 75:25 weighted average of (1) risk-adjusted DCF and (2) EV/EBITDA multiple analysis. We expect continued free cash flow growth in the near-term without any competition in EPP for at least three years. Clinuvel has multiple development streams ongoing to drive medium to long-term growth, for which we expect approval of Scenesse in vitiligo (~FY28) and launch of Neuracthel (~FY27) to be the largest potential growth drivers.

Based on our DCF forecast, the current CUV share price ascribes only a modest ~$50m in value to Clinuvel beyond the EPP franchise.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenue (A$m)	78.3	93.4	109.4	127.9
EBITDA (A$m)	42.5	52.0	64.1	78.4
NPAT (pre abnormals) (A$m)	30.6	38.0	44.3	54.3
Diluted EPS (cps)	59.1	73.3	85.6	104.8
EPS growth (%)	47%	24%	17%	22%
PE (x)	23.9	19.3	16.5	13.5
EV/EBITDA (x)	12.9	10.5	8.6	7.0
FCF yield (%)	6.4%	7.3%	7.3%	8.8%
Dividend (cps)	5.0	5.0	5.0	5.0
Franking (%)	100.0%	100.0%	100.0%	100.0%
Dividend yield (%)	0.4%	0.4%	0.4%	0.4%
ROE (%)	18.6%	19.0%	18.3%	18.5%

SOURCE: BELL POTTER SECURITIES ESTIMATES

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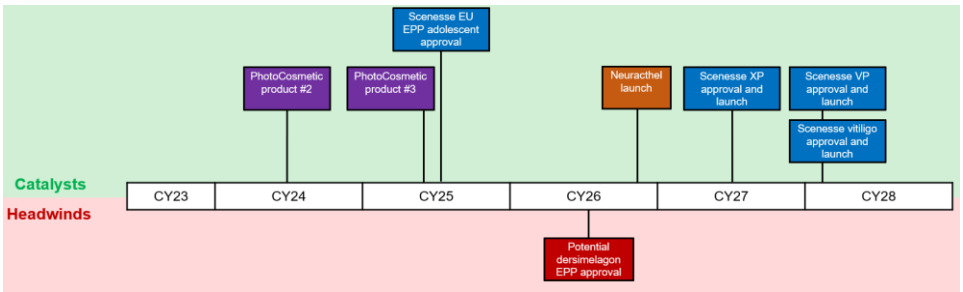
Investment Thesis

We initiate coverage on Clinuvel Pharmaceuticals (CUV) with a BUY recommendation and price target of $24.00. The key points underpinning our investment thesis are as follows:

- **Continued revenue growth and high margins.** Clinuvel's revenue has grown at a 3-year CAGR of 34% to A$78m while maintaining an attractive EBIT margin over 52%. This trend is expected to continue in the near-term as more new patients start on Scenesse and existing patients remain on Scenesse for several years.
- **Lack of EPP competition in the near-term**. While two alternative drug candidates are undergoing clinical trials in EPP, their approval remains uncertain and several years away, in our view. Therefore, we expect continued free cash flow growth in the near-term without any competition in EPP for at least another three years.
- **Potential expansion of Scenesse (afamelanotide) into additional indications**. Clinuvel are conducting multiple clinical trials with afamelanotide in four additional indications: vitiligo, XP, VP, and stroke. Early clinical data has been generated in these settings and if future pivotal trials generate supportive data, we estimate label expansions could be approved from ~FY28 (see Figure 1).
- **Neuracthel has an attractive risk-opportunity profile.** Clinuvel are developing Neuracthel as a generic version of ACTH. As a generic, the development risk is significantly lower than novel drug development, and we see strong commercial opportunity in a market occupied by two players generating ~US$600m in revenue.
- **Large and growing cash balance for in-licensing additional products.** Clinuvel's cash balance has grown consistently to A$157m as of 30th June 2023. This provides ample scope for internal R&D investment as well as inorganic pipeline expansion via in-licensing or acquiring complementary assets.
- **Generics still a long way off.** Scenesse patent exclusivity extends until at least ~FY28 in Europe and ~FY30 in the US, and possibly later if vitiligo approval is achieved. Additionally, Scenesse is a complex injectable implant with a very tightly controlled EPP distribution network. It remains unclear if any generics are in development, and we don't expect a steep sales cliff drop-off if they become available.
- **PhotoCosmetics potential blue-sky scenario.** There has long been demand for a consumer-friendly, risk-free tanning product from Clinuvel, having seen the tanning effect of Scenesse. Clinuvel are hoping to deliver on this highly sought after demand via its PhotoCosmetic product range. We have not forecast significant PhotoCosmetics revenues, however, if Clinuvel can deliver on a risk-free tanning product to broad consumer audiences, we expect significant commercial uptake.

Figure 1 below reflects our estimates for Clinuvel's approval and launch catalysts, as well as potential headwinds from competing EPP treatments.

Figure 1 - Clinuvel Approval/Launch Catalysts and Headwinds



Timing based on Bell Potter estimates. Commercialisation of (1) Scenesse in additional indications, (2) Neuracthel, and (3) dersimelagon is dependent on achieving successful clinical data and/or regulatory approval.

SOURCE: BELL POTTER SECURITIES ESTIMATES

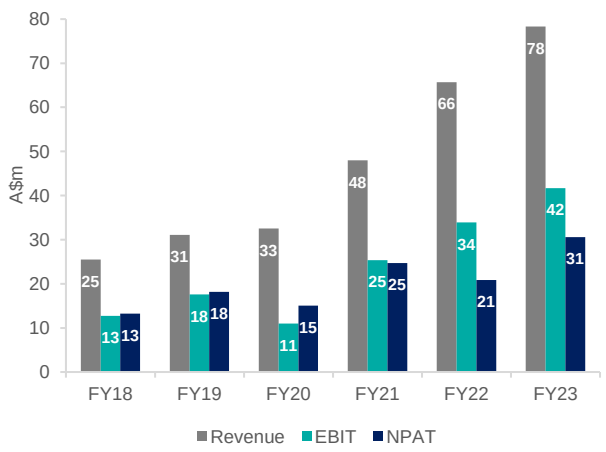
Financials

High Margins, Consistent Profits

Clinuvel is one of very few ASX-listed biopharma companies directly commercialising novel pharmaceuticals across major global markets. The company's relatively lean, vertically integrated business model has translated into very attractive profit margins on growing sales of their single pharmaceutical product, Scenesse.

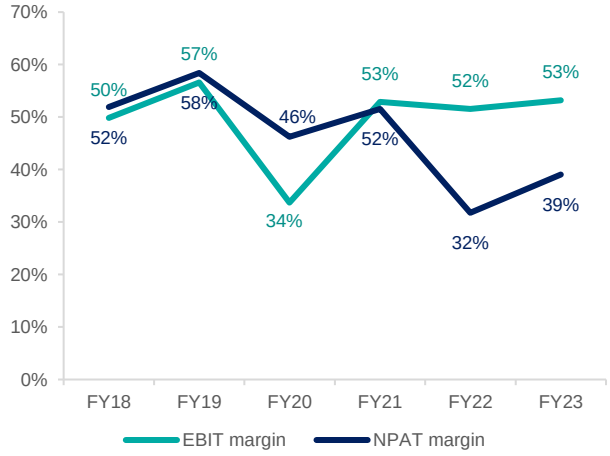
Clinuvel have been profitable for the last seven financial years, with a 52-53% EBIT margin over the last three financial years (see Figures 2A and 2B).

Figure 2A - Historical Revenue, EBIT, NPAT (A$m)



SOURCE: COMPANY DATA

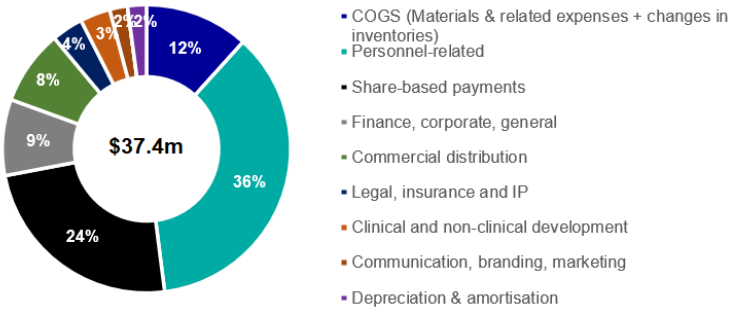
Figure 2B: Historical EBIT and NPAT Margins



SOURCE: COMPANY DATA

Clinuvel's pre-tax expenses were $37.4m in FY23 (+15% YoY). The largest contributor was personnel-related expenses of $13.6m, which represented 36% of total expenses (see Figure 3).

Figure 3 - Clinuvel FY23 Total Pre-Tax Expenses



SOURCE: COMPANY DATA. NOTE: WE ASSUME COGS = "MATERIALS AND RELATED EXPENSES" + "CHANGES IN INVENTORIES ETC".

$157m Cash for Diversification

After seven consecutive years of profitability and a conservative spending approach, Clinuvel have built a substantial cash reserve of A$157m as of 30th June 2023 with no debt. We expect Clinuvel will maintain exclusivity as the only EPP treatment for another ~3 years, resulting in continued free cash flow generation without any competition.

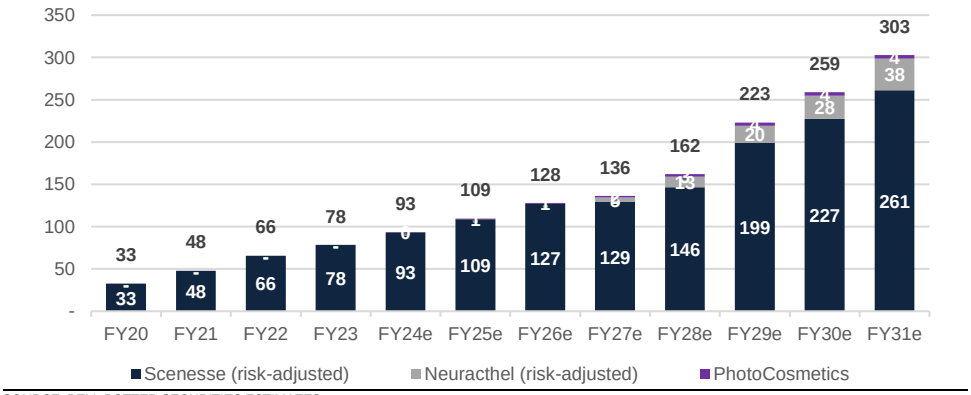
Clinuvel is very well positioned to fund internal clinical trials (such as in vitiligo), internalise manufacturing capabilities (guided to occur during FY24) and in-license/acquire externally developed assets to diversify commercial operations (guided within FY24-25).

Revenue forecasts

Our revenue forecasts (see Figure 4) are based on Clinuvel commercialising the following three products:

1. **Scenesse (afamelanotide)** in the following indications:
    a. Adult EPP: Ongoing commercialisation (no risk-adjustment)
    b. Adolescent EPP patients, EU only (80% risk-adjustment)
    c. Vitiligo patients, US only (33% risk-adjustment)
    d. XP patients (33% risk-adjustment)
    e. VP patients (25% risk-adjustment)
2. **Neuracthel**: US & EU commercialisation (infantile spasms & MS) (50% risk-adjusted).
3. **PhotoCosmetics**: Gradual ramp-up of single digit million sales (no risk-adjustment).

Figure 4 - Clinuvel Sales Forecast (A$m)



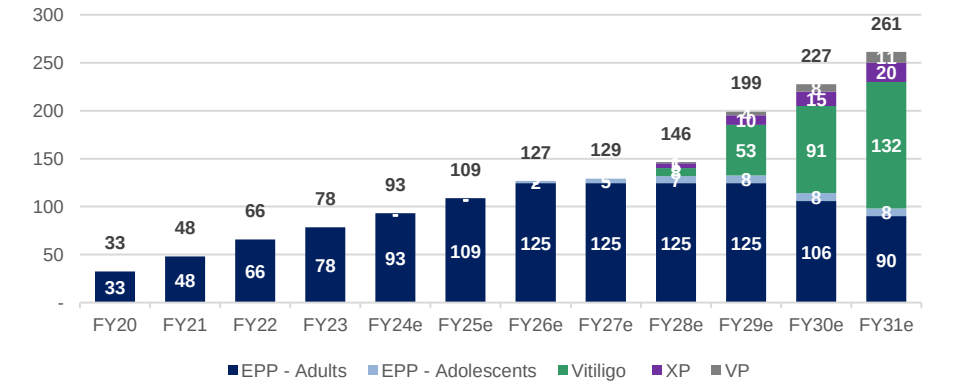
SOURCE: BELL POTTER SECURITIES ESTIMATES

We expect revenues to continue growing between 17-19% YoY over the next three years, driven by (1) new patients starting treatment as Clinuvel expands the number of prescribing centres and (2) existing patients remaining on Scenesse in the absence of alternative treatment options.

We have not included any revenue contribution from Prenumbra (afamelanotide) in the forecast period considering its relatively early stage of development.

A break down our Scenesse forecast is seen in Figure 5 below. Vitiligo represents the largest potential commercial opportunity. Our vitiligo sales forecast of A$132m in risk-adjusted FY31 sales reflects only ~2,200 vitiligo patients on treatment. Unadjusted vitiligo peak sales would be ~A$400m for the same number of patients.

Figure 5 - Risk-adjusted Scenesse Sales Forecast (A$m)



SOURCE: BELL POTTER SECURITIES ESTIMATES

Valuation

Our valuation is based on a 75:25 weighted average of 1) risk-adjusted DCF and 2) EV/EBITDA multiple analysis, as shown in Figure 6.

Figure 6 - Blended Clinuvel Valuation

Valuation Methodology	A$/share	Weighting (%)
DCF	25.5	75%
EV/EBITDA	19.6	25%
Final valuation	**24.0**	
Final target price (rounded)	**24.0**	
Current share price	14.1	
Implied upside/(downside)	**70%**	

SOURCE: BELL POTTER SECURITIES ESTIMATES

Discounted Cash Flow (DCF)

Our DCF is based on the risk-adjusted forecasts for Scenesse, Neuracthel and PhotoCosmetics, as shown on Figure 4 (previous page). The forecast period is to FY31 plus terminal value. WACC used is 10% and TGR 2%.

Figure 7 - DCF Forecast Period

Financial Year	FY24e	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e	FY31e
Operating cash flow	42.3	41.6	51.0	51.8	59.5	81.9	105.2	107.6
Capex	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)	(1.0)
Share-based payments	9.7	10.5	11.3	12.2	12.8	13.5	13.5	13.5
Free cash flow	**51.0**	**51.1**	**61.3**	**63.0**	**71.3**	**94.4**	**117.7**	**120.1**
Terminal value	-	-	-	-	-	-	-	1,651.8
Discount factor	1.10	1.21	1.33	1.46	1.61	1.77	1.95	2.14
PV of explicit cash flows	46.4	42.2	46.1	43.0	44.3	53.3	60.4	56.1
PV of terminal value	-	-	-	-	-	-	-	770.8
Total PV of explicit cash flows	391.8	*34%*						
Total PV of discounted terminal value	770.8	*66%*						
Enterprise value	**1,162.6**	***100%***						
Plus: Net cash/(debt)	156.8							
Equity value	**1,319.4**							
Total shares on issue (millions)	51.8							
Equity value per share	**25.5**							

FY23 weighted average ordinary shares used in diluted EPS

Equity value per share

		WACC				
		12.0%	11.0%	10.0%	9.0%	8.0%
Terminal Growth	0.0%	18.7	20.4	22.5	25.0	28.2
	1.0%	19.5	21.4	23.8	26.8	30.6
	2.0%	20.5	22.7	25.5	29.0	33.8
	3.0%	21.6	24.2	27.6	32.1	38.3
	4.0%	23.1	26.2	30.4	36.3	45.1

Premium/(Discount) to Current Share Price (closing price on 4/10/2023)

		WACC				
		12.0%	11.0%	10.0%	9.0%	8.0%
Terminal Growth	0.0%	33%	45%	59%	77%	100%
	1.0%	38%	52%	69%	90%	117%
	2.0%	45%	61%	80%	106%	140%
	3.0%	53%	72%	95%	127%	172%
	4.0%	64%	86%	115%	157%	219%

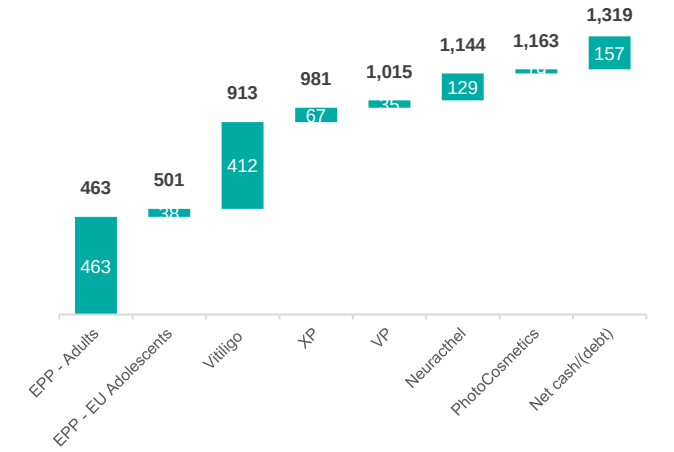
SOURCE: BELL POTTER SECURITIES ESTIMATES

The contribution of each indication and product to our DCF is shown in Figures 8A and 8B on the following page. The largest contributors to our DCF valuation are:

- 38% from EPP (Adults and EU adolescents);
- 31% from vitiligo; and
- 10% from Neuracthel.

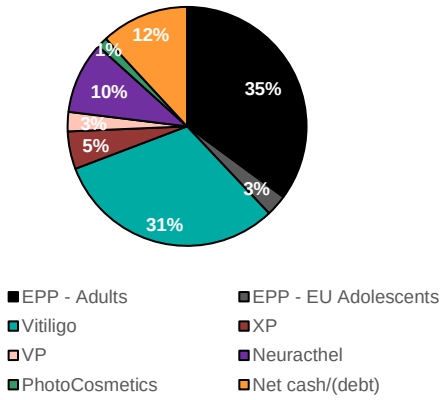
We also note that all non-COGS operating expenses are attributed to the existing EPP indication, which reduces its contribution as a percentage of the total.

Figure 8A – DCF Waterfall Chart (A$m)



SOURCE: BELL POTTER SECURITIES ESTIMATES

Figure 8B - DCF Components



SOURCE: BELL POTTER SECURITIES ESTIMATES

As shown in Figure 8A above, our DCF implies an enterprise value (EV) for the EPP franchise of A$501m (including both adults and EU adolescents). This value alone represents a mere 9% discount to CUV's current EV of A$549m. In other words, based on our EPP forecast, the current CUV share price ascribes only ~A$50m in value to Clinuvel's business beyond the EPP franchise.

EV/EBITDA Multiples Analysis

Clinuvel is currently trading at an FY24e EV/EBITDA multiple of 10.5x and a PE multiple of 19.3x based on our FY24 forecast. There are a lack of relevant ASX-listed comparables for Clinuvel due to the absence of companies directly commercialising novel drugs in US/EU markets, besides CSL. We have therefore selected a group of 20 international peers that are mid-to-large cap profitable biopharma companies directly commercialising novel drugs in the US/EU with relatively stable profits (Figure 9B).

Clinuvel's EV/EBITDA multiple of 10.5x is 20% below the peer group average of 13.2x. We also believe a ~25% premium to the peer group is justified for Clinuvel, implying an EV/EBITDA multiple of 16.5x. Reasons for the assumed premium for Clinuvel include:

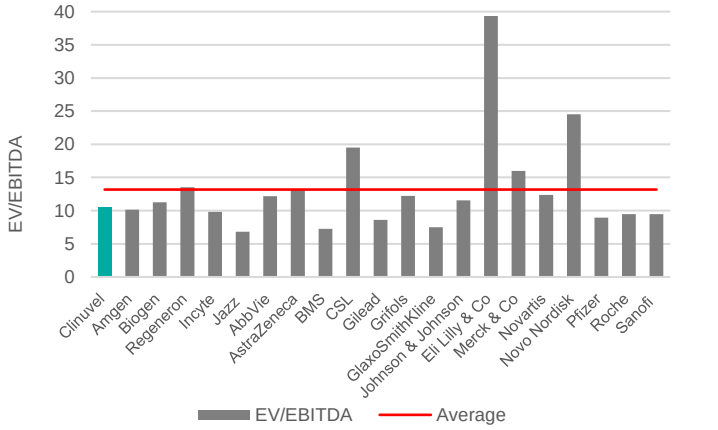
- strong growth profile only 3 years into US commercial launch;
- above-average EBIT margin of 53%;
- monopoly as the only available EPP treatment expected to continue for ~3 years; and
- lack of generic competition until at least the end of the decade at the earliest.

Figure 9A - EV/EBITDA Valuation Calculation

Clinuvel EBITDA (FY24e) ($Am)	52.0
Implied EV/EBITDA multiple (x)	16.5
Implied EV (A$m)	**858.4**
Plus: Net cash/(debt) ($Am)	156.8
Implied equity value (A$m)	**1,015.2**
Total shares on issue (millions)	51.8
Implied equity value per share (A$)	**19.6**

SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Figure 9B - Peer Group EV/EBITDA Multiple Analysis



SOURCE: COMPANY DATA AND BELL POTTER SECURITIES ESTIMATES

Scenesse – EPP

Approvals and Commercial Availability

Scenesse (afamelanotide) is approved and commercially available across Europe, USA, and Israel for treating patients with erythropoietic protoporphyria (EPP). It was first approved by the EMA in Dec 2014 (European launch June 2016), followed by FDA approval in Oct 2019 (US launch April 2020). Scenesse has therefore been available in Europe for 7 years and in the US for 3 years. As of Sep 2023, over 13,500 doses of Scenesse have been administered to >1,400 adult EPP patients.

Scenesse is the only approved treatment for EPP patients. Due to the lack of any alternative treatments, prior to its EMA approval in 2014, Clinuvel was able to distribute Scenesse in Italy from 2010 and Switzerland from 2012 under a special access program, and more recently in 2023 under a similar scheme in Canada.

What is Erythropoietic Protoporphyria (EPP)?

Erythropoietic protoporphyria (EPP) is a rare, inherited, lifelong disorder that causes extreme pain upon exposure to visible light. Severe photoreactive symptoms typically first appear in early childhood and can include burning, tingling, and itching of the skin, local edema (fluid build-up) and erythema. Phototoxic pain symptoms can develop within minutes, last for hours to days, and don't respond to conventional pain medications. As a result, EPP greatly impacts patients' quality of life and social functioning.

EPP is caused by an accumulation of protoporphyrin IX (PPIX) in the blood, which is highly activated by visible light. Accumulation of PPIX results from a mutation to the gene encoding the enzyme ferrochelatase, and as a result, ferrochelatase is unable to effectively convert PPIX into haem. In roughly 5-20% of EPP patients, the accumulation of PPIX can lead to liver cirrhosis and failure[1].

EPP is a rare disease estimated to occur in about 1 in ~140,000 people[2]. This translates into ~5,500 EPP patients across the US and EU, however, genetic screening has shown the true prevalence could be ~2-3 times more common than these estimates[3].

How Does Scenesse Work?

Scenesse (afamelanotide) is a synthetic peptide that stimulates melanocytes to produce eumelanin, which pigments the skin and is intended to protect against phototoxic reactions caused by sunlight. In simpler terms, it mimics a natural hormone to tell your skin to make more melanin. For EPP patients, increased eumelanin production by afamelanotide results in increased tolerance to sunlight and artificial light sources.

Afamelanotide is made up of 13 amino acids (AAs) that match the naturally occurring α-melanocyte stimulating hormone (α-MSH), except for two AA substitutions designed to increase afamelanotide's potency and half-life. Scenesse is formulated into a biodegradable 1.7cm long implant and subcutaneously injected every two months.

Clinuvel Business Model

With staff count of ~100, Clinuvel is a relatively lean, vertically integrated company, with internal functions across R&D, clinical, regulatory, and commercial distribution. Manufacturing is currently provided by US- and EU-based contract manufacturers,

[1] Wensink D., Liver involvement in patients with erythropoietic protoporphyria; Digestive and Liver Disease. 2022; 54(4).

[2] Clinuvel, Press Release: SCENESSE® continued in Germany, Jan 2022.

[3] Dickey et Al., Evidence in the UK Biobank for the underdiagnosis of erythropoietic protoporphyria. Genet Med. 2021 Jan;23(1):140-148.

however, management has stated on multiple occasions a desire to internalise manufacturing capabilities. The company is headquartered in Melbourne, has R&D facilities in Singapore (under the wholly owned subsidiary 'Vallaruix'), and clinical/commercial operations across Europe and USA.

Unlike many biotech companies, Clinuvel established a direct commercialisation model for Scenesse as opposed to out-licensing to an established partner. The company provides Scenesse only to centres that are trained and accredited by Clinuvel. There are currently over 50 of these centres across 39 US states, with the goal to establish up to 120 US centres for EPP patients as well as vitiligo (if approved). Clinuvel's direct commercialisation model has resulted in consistently high profit margins: over the last three years, estimated gross margins were over 90% and EBIT margins over 52%. The company also maintains a global EPP disease registry for pharmacovigilance purposes to ensure the use of Scenesse is tightly controlled to EPP patients only.

Pricing and Reimbursement

Clinuvel implement a uniform net pricing policy per jurisdiction. There is one price set for all of Europe, and another price across the US. In Europe, Clinuvel reported the price for Scenesse was €14k (A$23k) per implant in 2017 and later renegotiated this in 2021. We assume the current EU price is marginally higher than the 2017 figure at ~A$25k per implant. In the US, we assume net pricing post-rebates is ~10% higher than the EU price.

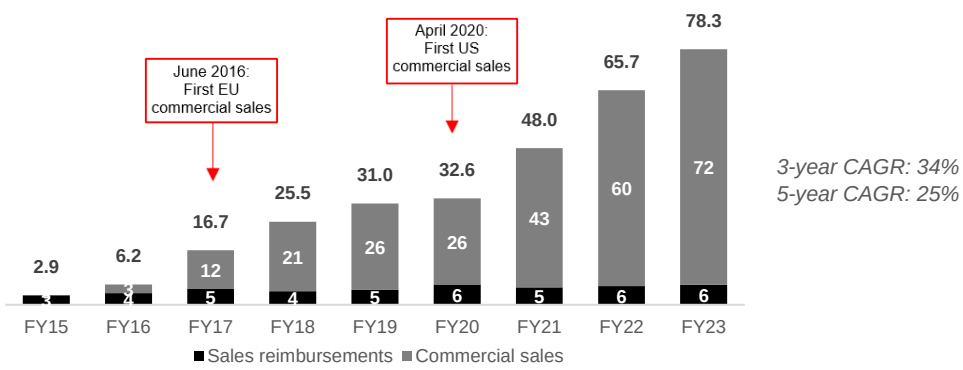
The European prescribing guidelines for Scenesse recommend no more than four implants per year, whereas the US guidelines do not include a recommended maximum. We therefore estimate average European annual price of A$102k assuming four implants per year, and average US annual price of A$141k assuming five implants per year.

On reimbursement, in the US, Scenesse is well covered by over 100 national and local private insurers as well as CMS. Billing codes are in place to reimburse EPP diagnosis, the drug itself, and implant administration, allowing for a streamlined insurance claim process. Clinuvel also established a Patient Assistance Program to directly assist with diagnosis, obtaining coverage, finding EPP centres and financial assistance. In Europe, Scenesse is covered by several payors; however, in the UK and Australia, the drug is approved but not covered by national insurance and therefore not commercially available to patients.

Scenesse Global Sales

Scenesse sales were $78.3m in FY23 (+19% YoY). Scenesse has been commercially available for 7 years in Europe and 3 years in the US. There was a clear increase in FY21 after the drug was launched in the US market. Sales have grown 19%, 37% and 47% in FY23, FY22 and FY21, respectively, as seen in Figure 10.

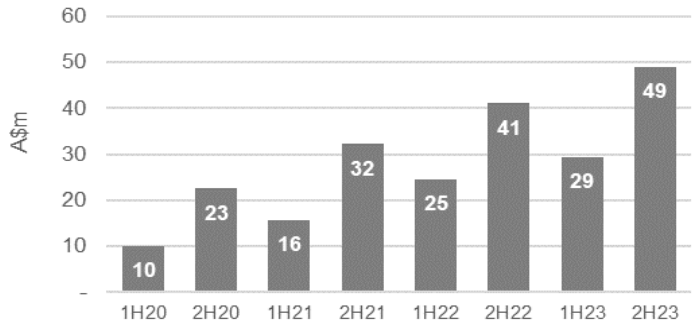
Figure 10 - Scenesse Global Sales (A$m)



SOURCE: COMPANY DATA

Sales are impacted by seasonality, observed through half-yearly sales (Figure 11). This is because Scenesse is more actively prescribed in summer months, most predominantly in Europe, where a maximum of 4 doses/year is recommended (US approval is uncapped).

Figure 11 - Scenesse Half-Yearly Sales (A$m)



Scenesse sales are typically larger in the second half of each FY due to greater use in northern hemisphere summer months, particularly in Europe.

SOURCE: COMPANY DATA

Regarding prescription volume, Clinuvel reported that in CY2022, prescription volume grew 32% in the US and 15% in Europe. Based on our above-mentioned pricing assumptions and FY23 sales, we estimate ~700 patients were on Scenesse in FY23, reflecting roughly ~15% of the estimated US and EU diagnosed adult EPP patients.

Competing Treatments for EPP

Scenesse is the only approved treatment for patients with EPP. One of the key risks to Clinuvel's sales is the potential for new treatments to gain approval and compete for market share of EPP patients. There are two companies in clinical development with novel treatments for EPP: Mitsubishi Tanabe Pharma America (MTPA) and Disc Medicine.

COMPETITOR 1: MITSUBISHI TANABE PHARMA AMERICA (MTPA)

MTPA's drug candidate is called Dersimelagon (or MT-7117). This is the most clinically advanced alternative drug candidate for EPP. Dersimelagon completed an initial Phase 3 trial in 2022 (n=184, results not reported) and is currently undergoing a Phase 3 extension trial monitoring patients for up to an additional 30 months. Dersimelagon is an oral, non-peptide treatment, administered daily, that activates the Melanocortin 1 receptor (MC1R) pathway, i.e. it acts upon the same receptor as Scenesse.

There have been some significant updates recently from MTPA:

i. Firstly, MTPA have recently changed the dose used in the Phase 3 extension study from 100mg to 200mg. This is unusual considering the trial began in Aug 2021, hence the dose has been changed midway through the trial. It is unclear whether the 200mg was the "high" dose used in the previous Phase 3 trial. However, we note that the Phase 2 trial used a 100mg "low" dose and 300mg "high" dose. In any case, this raises questions over MTPA's program as they appear to not have confirmed the final dose that would be sought for approval.

ii. Second, MTPA's parent company published an update in Aug 2023 stating the dersimelagon launch has been delayed from FY2023 to "FY25 and beyond"[4], where FY25 = year ending 31 March 2026. The extension study is expected to complete in Dec 2024; therefore, we expect earliest possible submission in mid-CY2025, followed by earliest approval in early-mid CY2026, assuming all goes smoothly.

iii. Third, the trial protocol has been changed to monitor patients for up to 30 months, it was previously a maximum of 24 months. We speculate this is likely due to the change in dose to 200mg.

[4] https://www.mcgc.com/english/ir/pdf/01660/01930.pdf

iv. Finally, we note that of the 184 patients in the initial Phase 3 trial, 151 are now being enrolled in the extension study, reflecting an 18% drop out rate. The extension study protocol originally targeted enrolment of 175 patients, so this reduction in planned enrolment from 175 to 151 reflects a greater than anticipated dropout rate. Clinuvel has also reported that some of the dersimelagon recipients have restarted afamelanotide treatment after ceasing dersimelagon treatment.

Looking at past results, data from dersimelagon's (MT-7117) Phase 2 trial (n=102) was published in NEJM and showed a significant increase in time to first prodromal (early warning) symptom: 82.7 mins, 74.0 mins, and 20.2 mins for 300mg, 100mg, and placebo doses, respectively[5]. This is a different endpoint to those measured in Clinuvel's Scenesse (afamelanotide) clinical trials. However, in a retrospective trial that surveyed 89 EPP patients taking Scenesse, 100% of 31 US patients and 81% of 58 Dutch patients reported an improvement in time to first prodromal symptom[6]. In terms of safety, MT-7117 resulted in increased rates of nausea, freckles, headache, and hyperpigmentation, with rates varying depending on the strength of the MT-7117 dose.

We conclude that dersimelagon could provide a convenient, oral alternative to the afamelanotide subcutaneous implant, if approved, which would be in ~early-mid CY2026 at the earliest. There appears to be significant uncertainty regarding the optimal dose (100mg vs. 200mg), which is surprising considering the Phase 3 stage of the asset. The higher than first expected 18% dropout rate also raises questions about tolerability/efficacy. We aren't expecting an efficacy advantage based on data to date and further safety data will be closely monitored, particularly regarding the rate of freckles for this chronic-use treatment. We also expect very stringent pharmacovigilance requirements and restrictions to be placed on dersimelagon if it is eventually approved, due to greater potential for off-label abuse as an oral treatment compared to the subcutaneous implant for Scenesse.

COMPETITOR 2: DISC MEDICINE (NASDAQ:IRON)

Disc Medicine's drug candidate is called bitopertin (DISC-1459) and is currently undergoing two Phase 2 clinical trials. Therefore, with a Phase 3 not yet initiated, we anticipate at least ~4-5 years until this treatment could be approved. Bitopertin is an oral glycine transporter (GlyT1) inhibitor that seeks to decrease the levels of metabolites underlying the cause of EPP. It is still relatively early days for development of this program however they did report initial data from an Australian Phase 2 (n=22) trial in June 2023 showing a reduction in PPIX levels and increase in symptom-free days[7]. Data from the second Phase 2 trial (n~75) are expected in early CY2024.

IP and Regulatory Exclusivity

A potential risk for Scenesse is generic competition. Based on patents owned and granted to Clinuvel, we estimate patent exclusivity covering the treatment of EPP patients with afamelanotide will expire in March 2029 (US) and Aug 2027 (EU). Additional patents have been granted covering the treatment of vitiligo, which expire in 2031 (US) and 2029 (EU). Regulatory exclusivity for Scenesse is expected to lapse prior to these patent expirations, in ~Oct 2026 (US) and ~Dec 2024 (EU).

Therefore, the earliest possible generic competition is not expected prior to ~FY28 in Europe and ~FY30 in the US, and possibly later if vitiligo becomes an approved indication.

We also note that as an injected bioresorbable implant containing a synthetic peptide, afamelanotide is more complex and potentially more difficult for generic developers to

[5] Balwani et. Al., Dersimelagon in Erythropoietic Protoporphyrias, The New England Journal of Medicine, April 2023.

[6] Wensink et. Al., EPP: time to prodrome, the warning signal to exit sun exposure without pain—a patient-reported outcome efficacy measure, Genetics in Medicine, September 2021.

[7] Disc Medicine, Corporate Presentation, August 2023.

replicate compared to conventional non-peptide small molecule drugs. It is unknown whether any generics are currently in development.

Lastly, Clinuvel's established and tightly controlled distribution network of EPP prescribers is a company-specific advantage that would likely help protect against generic competition. For these reasons, we don't expect a dramatic sales 'cliff' drop off for Scenesse resulting from generic competition.

Figure 12 - Clinuvel granted patents relating to afamelanotide

Patent	Title	Expected Expiration
US		
US 8334265 B2	Method of treatment of photodermatoses	March 2029
US 9345911 B2	Methods of inducing melanogenesis in a subject	Aug 2027
US 9801924 B2	Therapy for vitiligo	March 2031
EU		
EP 2865422 B1	Alpha-MSH derivatives for the treatment of photodermatoses	Aug 2027
EP 1789076 B1	Methods of inducing melanogenesis in a subject	Feb 2025
EP 2957292 B1	Therapy for vitiligo	March 2029

SOURCE: LENS.ORG

Clinical Data: Efficacy and Safety

Scenesse was approved based on increasing the amount of time EPP patients were able to spend in direct sunlight without pain. Three placebo-controlled clinical trials in EPP patients were evaluated by FDA and EMA in their reviews, however due to various GCP issues, only trial CUV039 was considered 'adequate and well-controlled', while the other two trials were considered supportive[8]. Some key clinical takeaways are as follows:

- In the pivotal trial CUV039 (n=93), subjects treated with Scenesse had a 91% increase in mean (and 70% increase in median) duration of direct sunlight exposure between 10:00-18:00 on days without pain. This was the primary efficacy endpoint of CUV039.
- In a long-term observational study in 115 European EPP patients, quality of life scores were 32% prior to Scenesse treatment, rose to 74% within six months of treatment, and remained between 69%-91% during a 6 year observation period.[9]
- Scenesse is generally well tolerated with the main AE differences compared to placebo including increased rates of nausea (19% vs. 13%), implant site discolouration (10% vs. 0%), and fatigue (6% vs. 1%).
- Scenesse has a high treatment continuation rate. In a European post-marketing registry, over 94% of patients remained on Scenesse as of July 2019[10].
- Scenesse often causes a tanning effect, which led the FDA & EMA to query the ability to blind clinical trials as several subjects on Scenesse had increased skin pigmentation.

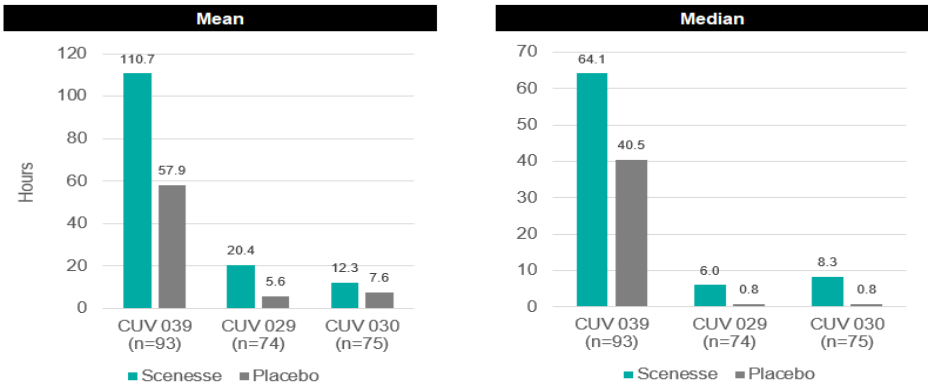
The figures on the following page show a selection of clinical data capturing the therapeutic effect of Scenesse.

[8] Source: Scenesse FDA NDA/BLA Multi-Disciplinary Review and Evaluation (2019); and EMA Public Assessment Report (2015).

[9] Biolcati et al., Long-term observational study of afamelanotide in 115 patients with erythropoietic protoporphyria, British Journal of Dermatology, 2014.

[10] TGA, Australian Public Assessment Report for Afamelanotide, March 2021.

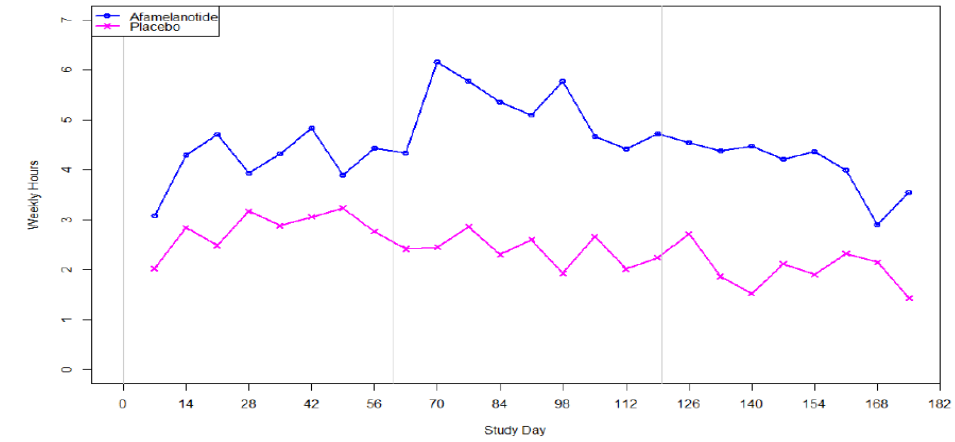
Figure 13 – Clinical trial results: Total hours of direct sunlight on days without pain



		Total hours of direct sunlight on days with no pain (hrs)			
Trial		**Scenesse**	**Placebo**	**% difference**	**p-value**
CUV 039 (n=93)	Mean	110.7	57.9	91%	0.055
	Median	64.1	40.5	58%	
CUV 029 (n=74)	Mean	20.4	5.6	264%	0.005
	Median	6.0	0.8	700%	
CUV 030 (n=75)	Mean	12.3	7.6	62%	0.010
	Median	8.3	0.8	1000%	

SOURCE: FDA SCENESSE NDA/BLA MULTI-DISCIPLINARY REVIEW AND EVALUATION, TABLE 54 (2019)

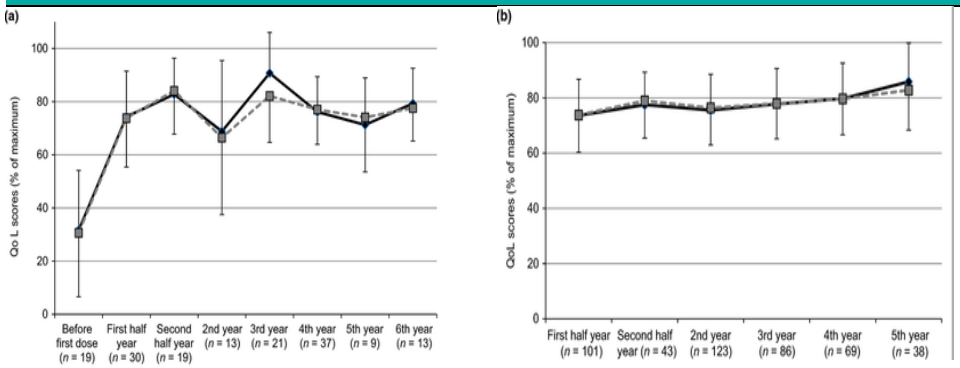
Figure 14 - Trial CUV039: Pain-free direct sun exposure per week over the treatment period



Vertical bars represent the nominal dosing days.
Source: Reviewer analysis.

SOURCE: FDA SCENESSE NDA/BLA MULTI-DISCIPLINARY REVIEW AND EVALUATION, TABLE 54 (2019)

Figure 15 - Quality of life questionnaires in long-term observational study



Quality of life (QoL) scores vs. treatment duration. All data are expressed as percentage of maximal QoL scores, thereby mean and SD are plotted. (a) Swiss patient group; (b) Italian patient group; n, number of questionnaires analysed per time span.

SOURCE: BIOLCATI ET AL., LONG-TERM OBSERVATIONAL STUDY OF AFAMELANOTIDE IN 115 PATIENTS WITH EPP, 2015, BRITISH JOURNAL OF DERMATOLOGY, 172, PP 1601-1612.

Scenesse – Vitiligo

Using the already approved dosage form of Scenesse, i.e., the subcutaneous 16mg implant, Clinuvel are attempting to expand Scenesse's approved indications into three new diseases (Vitiligo, XP and VP) as well as in adolescent EPP patients. In the next two sections of the report, we summarise the current development status, upcoming clinical development, and competitive landscape for each of the potential indication expansions.

What is Vitiligo?

Vitiligo is a chronic autoimmune condition that causes depigmented spots and patches of skin due to the immune system attacking its own melanocytes. In contrast to EPP, vitiligo is a far more prevalent disease, affecting ~1% of the population[11], resulting in over 2 million adult vitiligo patients in the US alone. Clinuvel plan to maintain its direct commercialisation model for vitiligo if Scenesse is approved for this indication. Clinuvel are looking to train up to 120 US accredited centres (currently >50) that could ultimately prescribe and administer Scenesse.

Scenesse Vitiligo Clinical Trials

Clinuvel first began conducting vitiligo clinical trials in 2011. Three clinical trials were completed between 2011-2016, all of which combined Scenesse with narrowband ultraviolet-B (NB-UVB) phototherapy. Subsequently, after several years of engagements with the FDA, a fourth trial, called CUV104 (n=6), was initiated in 2022 and is evaluating Scenesse as a monotherapy in vitiligo patients with darker complexion (Fitzpatrick IV-VI). Results from this trial are expected in FY24.

Past and potential future vitiligo trials are listed in Figure 16 below:

Figure 16 - Scenesse clinical trials in vitiligo

Trial Code	NCT	Phase	Start	Primary completion	N	Comment	Location
CUV101	NCT01382589	2	Sep 2011	July 2012	N=15	NB-UVB combo	Europe (3 sites)
CUV102	NCT01430195	1	June 2011	May 2012	N=56	NB-UVB combo	USA (3 sites)
CUV103	NCT04525157	2b	June 2014	Feb 2016	N=21	NB-UVB combo	Singapore
CUV104	NCT05210582	2	Oct 2022	Apr 2023	N=6	Monotherapy	USA
CUV105	TBD	TBD	~4Q CY23	TBD	~200	NB-UVB combo	TBD
CUV106	TBD	TBD	TBD	TBD	TBD	Monotherapy	TBD
CUV107	TBD	TBD	TBD	TBD	TBD	NB-UVB combo	TBD

SOURCE: CLINICALTRIALS.GOV AND COMPANY DATA

Clinical Trial CUV105

Clinuvel will soon initiate CUV105, their fifth and largest vitiligo trial (n=~200). Recruitment is expected to begin by the end of CY2023. The CUV105 study will be a two-arm trial comparing treatment with Scenesse combined with NB-UVB vs. NB-UVB monotherapy. The trial will target patients with darker skin complexion (Fitzpatrick skin type IV-VI). We await further details on the trial but expect recruitment criteria will include a minimum percentage of depigmented surface area, such as the 15% minimum in the CUV102 trial.

The CUV105 primary endpoint is likely to measure the number of patients achieving a 50% improvement in total vitiligo score, referred to as T-VASI50. Dosing is expected to be every month, compared to every two months for EPP patients. Patients will be dosed over a period of 5 months and monitored for an additional 6 months.

[11] Vitiligo. American Osteopathic College of Dermatology. Accessed February 14, 2022.

Future Vitiligo Trials

Clinuvel have previously mentioned that additional vitiligo trials, designated CUV107 and CUV106, may also be required to support FDA submission and approval. We expect trial CUV107 at a minimum will be initiated as a second, potentially pivotal trial (n=~200+) to support FDA vitiligo approval of Scenesse in combination with NB-UVB. The timing and specific details regarding CUV107 remain unclear, but it could take place somewhat concurrently to CUV105. We expect at least three years (CY2024-2026) of additional clinical development for Clinuvel to conduct these trials, followed by earliest potential approval in CY2028 for the expanded vitiligo indication.

Target Vitiligo Market

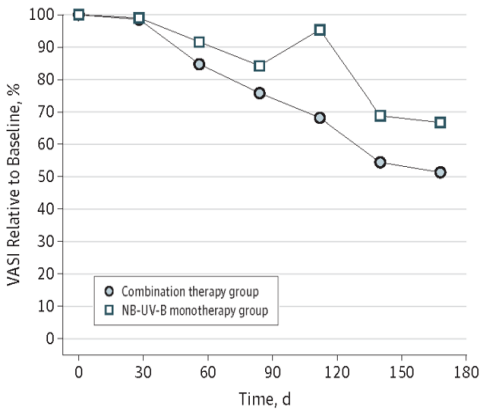
Of the ~2.6 million US adults with vitiligo, we estimate over ~60k US vitiligo patients fall into a directly addressable market for Scenesse with:

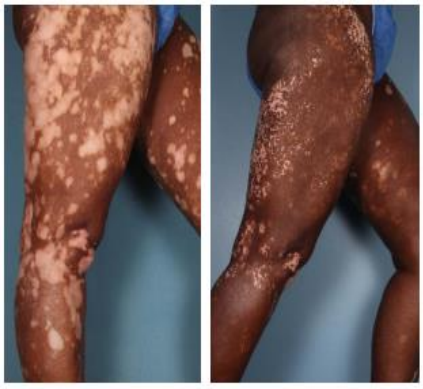
1) Fitzpatrick skin type IV-VI (~29% of US vitiligo patients[12]),
2) over ~15% affected surface area (~20% of vitiligo patients[12]), and
3) seeking treatment (~40% of vitiligo patients[13]).

Historical Data From CUV102 Trial

Past results from Clinuvel's two-arm CUV102 Phase 1 trial (n=55) showed a superior efficacy response in the Scenesse plus NB-UVB group after 24 weeks, as demonstrated by a 49% mean reduction in VASI at week 24 vs. 33% reduction in the NB–UVB monotherapy group (Figure 17). Additionally, patients with darker skin complexion (Fitzpatrick skin type IV-VI) had a more rapid response compared to those with Fitzpatrick skin type III complexion. Safety results demonstrated those receiving Scenesse had increased AEs of nausea (18% vs. 0%) and fatigue (11% vs 0%).

Figure 17 - Efficacy Results from CUV102 Vitiligo Trial (n=56)





Left: Mean change in Vitiligo Area Scoring Index (VASI) during the CUV102 treatment period. The first Scenesse dose was on day 28 (not day 0), followed by doses on days 56, 84 and 112.

Right: Repigmentation of a vitiligo patient's legs in the CUV102 study. The patients received 55 NB-UVB treatments and 4 Scenesse implants over six months. Images courtesy of the investigators.

SOURCE: LIM HW, GRIMES PE, AGBAI O, ET AL. AFAMELAN0TIDE AND NARROWBAND UV-B PHOTOTHERAPY FOR THE TREATMENT OF VITILIGO: A RANDOMIZED MULTICENTER TRIAL. JAMA DERMATOL. 2015

[12] Incyte, The Mental Health and Psychosocial Burden Among Patients Living With Vitiligo in the United States: Findings From the Global VALIANT Study, March 2022, https://www.incytemi.com/document/Poster/AAD%202022%20-%20VALIANT%20Mental%20Health%20US%20Data.pdf

[13] Clinuvel, Sydney Soiree Presentation, Oct 2022.

Competing Vitiligo Treatments

Unlike EPP, there is an alternative drug to Scenesse called Opzelura (ruxolitinib) that was approved in 2022 as the first treatment for vitiligo patients and is now commercially available. Several other treatments are also in clinical development as shown in Figure 18.

Figure 18 - Approved treatments and development candidates for vitiligo^

Company	Treatment	Development Stage	Comment	Efficacy	Safety
Incyte	Opzelura (ruxolitinib)	**FDA approved** (July 2022). EMA approved (Apr 2023). Ph2 (n=55) in combo with NV-UVB ongoing.	First FDA approved treatment for vitiligo (Jul 2022). JAK inhibitor. Topical cream, monotherapy, twice daily. Patients with <10% affected body surface area and >12yrs age. First approved for atopic dermatitis (Sep 2021). 2Q23 sales of ~$80m, 2yrs since first approval. List price $2k/tube (=~$50k annual list price if used fortnightly).	From two Ph3 trials (n=458, n=344): 30% and 31% of Opzelura patients achieved F-VASI75 at week 24, compared to 7% and 11% in placebo.	Blackbox warning based on data from oral version about risk of serious infections, major adverse cardiovascular events, thrombosis, cancer and mortality. Opzelura showed higher rate of the following TEAEs vs placebo: acne, pruritus, nasopharyngitis, headache, UTI, erythema.
Pfizer	Litfulo (ritlecitinib) / B7981040	**Phase 3 initiated** (n=600) in Dec 2022. Primary completion June 2025. Ph2 (n=364 compete)	Oral capsule (50mg) monotherapy. JAK inhibitor. Patients >12yrs. FDA approved for alopecia (June 2023)	Phase 3 co-primary endpoints: F-VASI75 and T-VASI50 at week 52.	Similar blackbox warnings to Opzelura for alopecia indication.
Avita	RECELL (device)	**FDA premarket approval** in June 2023. Ph3 trial (TONE, n=100) in progress to support reimbursement.	Approved as a single-use device, not a therapeutic. Patients >18yrs. Reimbursement and therefore commercial availability not expected until 2025.	Comparison of RECELL + NB-UVB vs. NB-UVB alone in different depigmented areas: 56% (RECELL + NB-UVB) achieved >50% repigmentation vs. 12% (NB-UVB alone).	N/A
Incyte	Povorcitinib / INCB54707	**Phase 2** data (n=171) reported March 2023.	Oral JAK1 inhibitor not yet approved for any conditions.	Ph2b data: -19% reduction in T-VASI at week 24 (15mg dose) vs. +2% for placebo. 6-15% achieved T-VASI50 at week 24 vs. 3% for placebo.	No serious TEAEs considered related to povorcitinib.
AbbVie	Rinvoq (upadacitinib)	**Phase 2** data expected 2H CY2023.	Oral JAK inhibitor first approved in 2019. Currently approved for RA, PsA, AS, UC, CD, atopic dermatitis.	N/A	Similar blackbox warnings to Opzelura for approved indications.

SOURCE: COMPANY DATA.
^ EXCLUDES APPROVED UV PHOTOTHERAPY DEVICES APPROVED BY THE FDA UNDER 510(K) REGULATORY PATHWAY

Clinuvel's directly addressable vitiligo patient cohort is far larger than EPP (~60k vs. <3k US patients), with greater scope for multiple treatment options. Unlike the approved/in-development JAK inhibitors, Scenesse is not an immune suppressant, and therefore could provide a valuable treatment alternative, particularly for vitiligo patients at high-risk of infections or illness. However, we do note that recent data showed Opzelura was relatively well tolerated after 104 weeks, with higher rates of respiratory tract infections and application site reactions vs. placebo[14].

Opzelura Commercial Precedent

Opzelura has a US list price of US$2,000 per 60mg tube of cream, with gross-to-net discounts stated to be roughly 50%[15]. Each tube is used no more than once per week. Hence, assuming a patient uses one tube per fortnight, the annual list price is ~US56k with a net price after rebates roughly half (~US$28k). Opzelura generated ~US$80m in quarterly sales (annualising at ~US$340m) across its two indications, after ~22 months on the market.

Unlike Opzelura, if Scenesse is approved for vitiligo, we expect the label to be restricted for use in patients with darker skin complexions and larger vitiligo affected surface area. It may also be predominantly used by patients at high risk of infections that have failed to respond to Opzelura or other JAKs.

[14] Incyte, March 2023, Revolutionizing the Treatment of Vitiligo

[15] https://www.fiercepharma.com/pharma/discounts-incytes-eczema-cream-opzelura-improve-year-end-goal-still-way-go

Vitiligo Summary

We view vitiligo as the most commercially attractive of the potential Scenesse label expansions. It has been a slow vitiligo journey to date for Clinuvel, with the first trial starting in 2011. We expect at least two potentially pivotal trials will be initiated by Clinuvel (CUV105 and CUV107) prior to approval. Hence the earliest potential launch is not expected before CY2028, by which time there will likely be at least two alternative treatment options available. However, the large addressable vitiligo market is supportive of multiple therapy options treating many thousands of patients.

Unlike Opzelura, if Scenesse is approved for vitiligo, we expect the label to be restricted for use in patients with darker skin complexions and larger vitiligo affected surface area (~60k addressable US patients). We expect usage may predominantly be for patients at high risk of infections that have failed to respond to Opzelura or other JAKs. At an annual US price potentially >A$150k, even treating 1k patients (which is <2% of the addressable market) will lead to additional revenues over A$150m, with potential for greater uptake beyond this.

Scenesse – Additional Indications

Xeroderma Pigmentosum (XP)

Xeroderma pigmentosum (XP) is an ultra-rare inherited disease affecting ~1 in 1 million people (~1,000 patients across US, EU, LatAm). People with XP have one of 8 genetic mutations that stop the skin from repairing damage from ultraviolet radiation (UVR). As a result, XP patients are 10,000 times more likely to develop non-melanoma skin cancer and 2,000 times more likely to develop melanoma skin cancer, compared to unaffected individuals[16]. Depending on the type of genetic mutation, patients are categorised into eight distinct complement groups (XP-A to XP-G and XP-V).

Symptoms develop in early childhood and include extreme sunburn after just minutes in the sun, leading to blistering and redness that can last for weeks. By age 2, children often develop freckling in sunlight-exposed areas, dry skin, and pigmentation. By age 10, most children have developed at least one skin cancer. Patients' eyes also become highly sensitive to UVR. Median life expectancy is 30 years[17].

There is no approved treatment for patients with XP. Clinuvel is the only pharmaceutical company evaluating a drug candidate in XP patients as per clinicaltrials.gov.

CLINICAL TRIALS

Figure 19 - Afamelanotide Clinical Trials in Xeroderma Pigmentosum

Trial Code	NCT	Phase	Subjects	N	Start	Results	Comment
CUV151	NCT05368857	1	Healthy volunteers	9	Jan 2022	FY24	Exposure to UVR before and after treatment.
CUV152	NCT05370235	2	XP-V & XP-C	6	March 2022	FY24	Dosing every 2 weeks.
CUV153	TBD	TBD	XP-V & XP-C	6	TBD	TBD	TBD
CUV154	TBD	TBD	XP-V & XP-C	20	TBD	TBD	TBD
CUV156	NCT05159752	2	XP-C	6	Oct 2021	FY24	Dosing every 2 weeks.

SOURCE: COMPANY DATA AND CLINICALTRIALS.GOV

Clinuvel reported initial results from the CUV156 trial in Jan 2023 which showed a decrease in UV-induced DNA skin damage in XP-C patients following treatment. Across various measurements, patients showed reduction in CPD photodamage (3/3 patients), increase in p53 tumour suppressor gene (2/3 patients), increase in gamma-H2AX expression (3/3 patients), reduced sunburn, and increased melanin density.

Results from the CUV151 healthy volunteer study were announced in Feb and Aug 2023. Subjects were exposed to UVR before and after Scenesse treatment. Following treatment with Scenesse, data showed a significant reduction in DNA photodamage shortly after irradiation (15 minutes) and over a longer period (48 hours), as well as a reduction in UV-erythema (sunburn), compared to baseline.

Additional results from the three ongoing trials (CUV151, CUV152 and CUV156) are expected in FY24. Following these results, and assuming the data is supportive, additional clinical trials (i.e., CUV153 and CUV154) will be undertaken to allow for a dossier submission to expand the approved Scenesse indication(s) to include XP. We therefore expect further XP clinical development will take place over at least the next 3 years (FY24-26) with earliest approval and launch in FY28.

[16] https://medlineplus.gov/genetics/condition/xeroderma-pigmentosum/#frequency

[17] Clinuvel, Afamelanotide reduces DNA photodamage in xeroderma pigmentosum, Jan 2023.

SUMMARY

In conclusion, XP represents a desperately in need, small patient population, with no alternative treatments currently available or in clinical development. We note dosing of afamelanotide in the CUV152 and CUV156 trials is every 2 weeks, compared to every 2 months for EPP, opening the potential for higher dosing frequency and pricing for this population. We expect further clinical development is required over the next 3 years, resulting in earliest possible launch in this indication to be in ~FY28.

Variegate Porphyria (VP)

Like EPP, variegate porphyria (VP) is a rare inherited porphyria disorder. For individuals with VP, porphyrins accumulate in the liver and can be transported to other parts of the body to affect the nervous system and skin, resulting in the highly variable symptoms of a porphyria attack. VP is caused due to a deficiency in the enzyme PPOX involved in the haem biosynthesis pathway.

Symptoms vary greatly among patients and typically develop in adulthood. Affected individuals develop cutaneous (skin) or neurological abnormalities or both. Cutaneous symptoms are more likely to be chronic compared to neurological symptoms that typically occur as acute attacks lasting days or weeks. Blistering of the skin on hands and face and sensitivity to sunlight are the most common cutaneous symptoms. Neurological impacts can include various abdominal symptoms (nausea, pain, constipation), anxiety and restlessness.

The reported prevalence is 1 in ~100,000 individuals across Europe, and therefore a roughly similar number of patients are affected compared to EPP: approximately ~5,000-10,000 across the US and Europe[18].

CLINICAL TRIALS

Clinuvel started their first clinical trial in VP patients in May 2023. The Phase 2 trial (n=6, NCT05854784) is called CUV040 and is expected to provide first efficacy results in CY2024. Patients are being dosed with Scenesse every month. Following the review of results from CUV040, additional clinical trial(s) would need to be conducted before submitting for a label expansion of Scenesse into this patient population. Similar to Clinuvel's XP program, we therefore expect further clinical development in VP will take place over at least the next ~3 years (FY24-26) with earliest approval and launch in FY28.

AVAILABLE THERAPIES

There is one therapy called Givlaari (givosiran) that was FDA/EMA approved in 2019/2020 for treating acute hepatic porphyria, which encompasses four different porphyria subtypes, including VP. Givlaari is a small interfering RNA (siRNA) treatment, commercialised by Alnylam (NASDAQ:ALNY) with an annual list price of ~US$575k (or US$39k per monthly vial). Givlaari generated US$58m in quarterly 2Q23 revenues across 570 patients worldwide on the treatment.[19]

In the ENVISION Phase 3 trial (n=94), patients on Givlaari had a 70% reduction in porphyria attacks compared to placebo, and 50% of patients on Givlaari were attack-free during the first six months compared to 16% of patients on placebo. However, there are safety concerns with the treatment, with substantially higher rates of nausea, injection site reactions, rash, serum creatinine and fatigue.

Beyond Givlaari, there are no other pharmaceutical companies besides Clinuvel in the clinic with a drug candidate for VP as per clinicaltrials.gov.

[18] Orphanet, Porphyria variegate, 2009.

[19] Alnylam 2Q 2023 Earnings Announcement.

SUMMARY

We estimate another ~4 years until Scenesse could be approved as the second available treatment for VP patients. Initial efficacy data will be crucial to inform whether Scenesse improves neurological (abdominal) symptoms associated with VP and/or the cutaneous symptoms. If ultimately approved, we see scope for Scenesse uptake as an alternative treatment to Givlaari, particularly for VP patients suffering from chronic cutaneous symptoms that are not well controlled by Givlaari.

Adolescents with EPP

Scenesse is currently only approved for treating adults with EPP. Clinuvel submitted an application for European label expansion of the existing 16mg drug in 12-17 year olds in Sep 2022. However, in Sep 2023, Clinuvel announced EMA want additional clinical data before granting approval. Clinuvel will now conduct a post-authorisation, single-dose trial (called CUV052) in 12 adolescent EPP patients across three centres. Results are expected to be reported to the EMA in CY2024, which we estimate would likely lead to approval no earlier than CY2025.

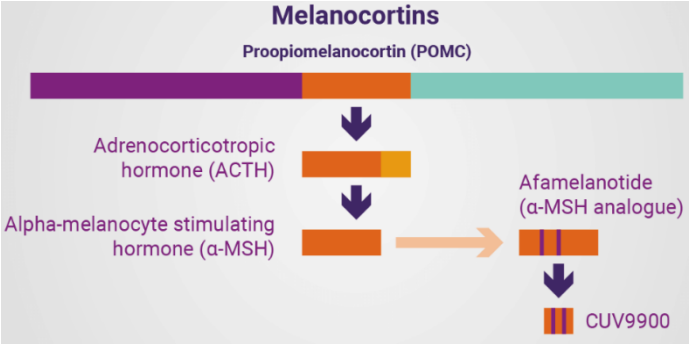
With ~10% of all EPP patients estimated to be between 12-18 years old, this remains a significant patient population that have not yet been able to access Scenesse. We estimate there are ~300 European adolescent patients, translating into a total addressable market opportunity of ~A$30m annually. Therefore, we estimate the expansion into European adolescents could readily add >A$10m in Scenesse annual sales. It remains unclear whether the CUV052 trial will also support US label expansion for 12 to 17 years.

Neuracthel (ACTH)

Clinuvel are developing Neuracthel, an additional pharmaceutical product with a different active substance to afamelanotide.

Like afamelanotide, Neuracthel is a synthetic analogue of a melanocortin hormone in the human body, referred to as adrenocorticotropic hormone (or ACTH). ACTH is related to afamelanotide in that ACTH is the precursor peptide to α-MSH (Figure 20). The first 13 amino acids of ACTH are the same that comprise α-MSH.

Figure 20 - ACTH is the precursor peptide to afamelanotide



All melanocortin hormones are derived from the precursor peptide proopiomelanocortin (POMC). The naturally occuring ACTH hormone has 39 amino acids. α-MSH is a derivataive of ACTH comprised of the first 13 amino acids of ACTH.

SOURCE: COMPANY DATA

It's important to note that Neuracthel is being developed as a generic drug, not a novel drug like Scenesse.

As a generic, Clinuvel will not be required to conduct clinical safety and efficacy trials for Neuracthel, but instead demonstrate through analytical and human PK testing that the compound they have developed is comparable to existing ACTH products. This means the development path for Neuracthel is far shorter, cheaper, and less risky compared to a traditional novel medicine.

Clinuvel announced in Jan 2023 they had advanced manufacturing activities with their partner for Neuracthel regarding method and process development. Throughout CY2023, Clinuvel will produce Neuracthel at commercial scale under cGMP standards. Analytical data from these batches will then be used to support an application for approval by regulators. The first indications sought for approval will be in children with infantile spasms and adults with relapsing episodes of multiple sclerosis.

Clinuvel are developing two different dosage forms of Neuracthel: an instant release and a modified release formulation.

While specific details about planned development remain unclear, we see potential for this drug to be approved in late-CY2026, based on ANDA submission in late-CY2024 and ~24 months for FDA review and approval thereafter.

WHAT IS ACTH?

ACTH is a naturally occurring hormone that triggers the production of cortisol, enabling the combat of stress and regulation of immune responses, maintenance of blood pressure, moderation of blood sugar, and regulation of metabolism.

As a therapy, ACTH is an alternative to corticosteroids that controls rheumatic and autoimmune disease flare ups. Like corticosteroids, ACTH doesn't slow the progression of the disease.

THE ACTH BACKSTORY

ACTH was first approved as a therapeutic agent in the 1950s as a pig derived hormone. Approved drugs containing ACTH or its analogues – under the brand names Cortrosyn,

Synacthen, and Acthar – have since been approved across the USA, Europe and APAC. ACTH analogues are available as liquid and gel formulations for use in severe chronic and acute neurological, endocrinological and degenerative disorders.

There are two commercial case studies worth noting regarding ACTH:

1. **Acthar**. HP Acthar Gel was originally approved in 1952 and controversially subjected to dramatic price hikes by Questcor and later Mallinckrodt. In 2000, Questcor acquired the drug at a time when it was being sold for $40 a vial. By 2013, Questcor had raised the price to $23,000 a vial. Later acquired by Mallinckrodt, the price rose to $40,000 a vial. As a result, in 2018, Acthar generated US$1.1 billion in annual sales with limited competition[20]. By 2022, Acthar sales had decreased to US$516m.
2. **Cortrophin Gel**. ANI Pharmaceuticals (NASDAQ:ANIP) received FDA approval in Nov 2022 for Cortrophin Gel, a pig derived ACTH drug. The drug was approved for chronic autoimmune disorders, including MS, rheumatoid arthritis, and nephrotic syndrome. In its first year of sales in 2022, Cortrophin generated US$42m in revenue. 2023 revenue guidance for Cortrophin is US$90-100m as of Aug 2023[21].

Beyond these two products, a synthetic ACTH product called Cortrosyn (from Amphastar) is approved for use as a diagnostic agent in patients expected to have adrenocortical insufficiency, but not approved as a therapeutic drug.

Lastly, Synacthen Depot is another synthetic ACTH product that was previously commercialised by Novartis outside the US for therapeutic uses. Questcor acquired Synacthen Depot from Novartis in 2014 and effectively shelved its commercial rollout, thereby eliminating competition for their own Acthar product.

NEURACTHEL COMMERCIAL OPPORTUNITY

We see promising opportunity Neuracthel to compete with the two porcine-derived ACTH products (Acthar, Cortrophin) which will generate ~US$600m in sales in 2023. Particularly interesting is the case study of Cortrophin, which is on track to generate ~US$100m in revenues in 2023 in its second year on the US market. An unknown will be how Clinuvel plan to commercialise Neuracthel. The intended use in infantile spasms and multiple sclerosis will involve different prescribing channels and commercialisation efforts compared to the rare disease EPP for Scenesse.

[20] https://www.fiercepharma.com/pharma/mallinckrodt-places-hopes-modernized-acthar-generic-unit-facing-bankruptcy

[21] ANI Pharmaceuticals, 2Q 2023 Financial Results Press Release, 9th Aug 2023.

Prenumbra and Preclinical Pipeline

Prenumbra

Clinuvel are using the same active ingredient of Scenesse, afamelanotide, and reformulating it into a liquid, fast-acting formulation for use in acute-care, referred to as 'Prenumbra Instant'. The novel formulation is first being assessed in patients with Arterial Ischaemic Stroke (AIS).

Clinuvel's hypothesis is that melanocortins such as afamelanotide could protect brain tissue and increase blood flow following a stroke event, as well as imparting anti-oxidant and anti-swelling activity that may limit the extent of brain damage and disability[22].

CLINICAL TRIALS

Clinuvel completed an open label, single-arm Phase 2a clinical trial in May 2022, called CUV801, in six mild-to-moderate adult AIS patients. This trial evaluated the subcutaneous 16mg afamelanotide implant. Patients were administered afamelanotide within 24 hours of suffering a stroke and evaluated for six weeks. One of the six patients passed away from a second stroke which was determined to be unrelated to afamelanotide.

In March 2023, Clinuvel initiated its second clinical trial in up to 12 AIS patients who were ineligible for Intravenous Thrombolysis (IVT) or Endovascular Thrombectomy (EVT). This Phase 2, single-arm trial, called CUV803, is evaluating the Prenumbra Instant liquid formulation. A flexible and tailored dosing quantity will be used for each patient. Patients will receive Prenumbra Instant subcutaneously for up to 5 consecutive days after the stroke and will be assessed for safety and efficacy over 42 days. The single-arm trial will evaluate endpoints including safety, level of stroke impairment (by NIHSS), daily living activities, cognition (by MMSE) and imaging. In May 2023, Clinuvel reported that three patients had been treated in the trial and showed functional improvement following Prenumbra dosing.

LARGE MARKET OPPORTUNITY, RELATIVELY EARLY STAGE

While early clinical results in the CUV801 and CUV803 single-arm trials support continued evaluation, we expect at least another 5 years of development activities will be required before Prenumbra could be approved in AIS. Due to this longer and more uncertain development pathway, as well as limited data to date, we have not incorporated Prenumbra product sales in our forecast and valuation methodology at this time. However, we do acknowledge the large potential market, with over 12 million AIS strokes annually, of which only ~25% of patients receive IVT or EVT treatment[23].

Additional preclinical pipeline

Beyond the abovementioned pharmaceuticals products (Scenesse, Neuracthel and Prenumbra), Clinuvel also list several 'second-generation' melanocortin pharmaceutical products in their preclinical pipeline. The products are α-MSH analogues and referred to as 'CUV9900' and 'Parvysmelanotide (VLRX001), phimelanotide'. One or several of these may be topical skin treatments. CUV9900 was first announced in 2010 but has not been evaluated in clinical trials since. Similar to afamelanotide, these products are smaller peptide units derived from ACTH. Considering the limited details and preclinical stage of these products, we have not included them in our forecasts or valuation methodology.

[22] Clinuvel Press Release, CLINUVEL escalates PRÉNUMBRA® to moderate/severe stroke patients, 9th May 2023.

[23] Clinuvel, Technical Note – CUV803 Study and AIS, 20th March 2023

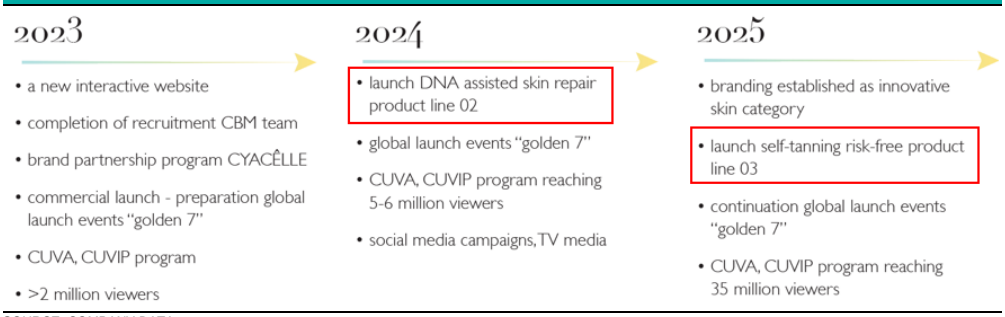
PhotoCosmetics

Leveraging its experience in photomedicine pharmaceuticals, established through the R&D and commercialisation of afamelanotide and other melanocortins, Clinuvel are launching a range of 'PhotoCosmetic' consumer products across three product lines:

1. **CYACÊLLE:** Designed to provide broad spectrum solar protection against ultraviolet (UVA and UVB) and high energy visible (HEV) light. This is a leave-on cream that is particularly targeted to individuals who are intolerant to sunlight or at high risk of developing skin cancer. For example, people who spend excessive time in high UVR exposure environments (snow, water), or have a family history of skin cancer, or immune-suppressed.
2. **DNA Repair Products:** Second, Clinuvel plan to launch a range of products that aim to prevent and repair cellular DNA damage caused by solar exposure.
3. **Melanogenic Products:** Third, Clinuvel plan to launch a first of its kind risk-free self-tanning product.

The above products are not pharmaceuticals and will be available for purchase online by any individual (at least those in six European countries, for now). In March 2023, the first of the PhotoCosmetics, called CYACELLE [pictured left], was launched in a European pilot program, initially free-of-charge to EPP and XP patients as an adjuvant to Scenesse. CYACELLE is also available via Clinuvel's website at a price of €74 for a 100ml bottle. The product generated A$9k in FY23 sales after ~3-4 months of the pilot launch.

Figure 21 - Clinuvel CBM Plans Across CY2023-2025



SOURCE: COMPANY DATA

As per the above Figure 21, Clinuvel plan to launch the second DNA Repair product line in CY2024 and third self-tanning product line in CY2025.

UNCHARTERED WATERS

It is difficult to forecast the potential of these consumer products, however, we confidently expect the greatest consumer demand will be for the sun-free, self-tanning product line #3. If Clinuvel can develop a product that delivers on this promise for risk- and sun-free tanning, we have no doubt that this will garner substantial commercial interest and publicity.

In order to roll out their PhotoCosmetics range, Clinuvel established an internal marketing division, referred to as the 'Communications, Branding, & Marketing (CBM) team. The CBM division will comprise ~25 staff, led by Marga Bibiloni (ex-Louis Vuitton and Burberry).

Acknowledging the considerable attention and resources allocated to Clinuvel's digital marketing unit, and the first consumer product rollout now underway, we have included a gradual ramp-up of low single digit million sales for Clinuvel's PhotoCosmetics during the forecast period. We await further details on the full-scale rollout of CYACÊLLE and launch of product lines #2 and particularly #3 before attributing further value to this business unit.

Company Description & Risks

Company Description

Clinuvel is a pharmaceutical company directly distributing its lead drug SCENESSE (afamelanotide) across Europe, USA and Israel, for patients with the rare disease Erythropoietic protoporphyria (EPP). Clinuvel are looking to diversify revenues through 1) undertaking clinical trials to expand the approved use of afamelanotide in additional indications (vitiligo, XP, VP and stroke); 2) developing additional pharmaceutical products (e.g. Neuracthel); and 3) launching a range of non-pharmaceutical consumer products, referred to as 'PhotoCosmetics'. The company was founded in 1999 as EpiTan and changed its name to Clinuvel in 2006 after shifting strategy to develop afamelanotide for medical conditions such as EPP. Philippe Wolgen has served as CEO since 2005. Clinuvel's primary listing is on the ASX (from 2001) and also trades on the Borse Frankfurt in Germany (as UR9) and the OTC securities market in the USA as a Level 1 American Depositary Receipt (CLVLY).

Company risks include but are not limited to:

- **Competitor risk**: While there are no alternative treatment options currently approved for EPP patients, there are two other companies undergoing clinical trials in EPP for their respective drug candidates. Competitor approval remains uncertain, however, if alternative EPP treatments do end up achieving approval and commercial availability, they would compete for market share of EPP patients with Scenesse.
- **Clinical risk**: Clinuvel is conducting multiple clinical trials to expand the use of afamelanotide in vitiligo, XP, VP and stroke. While initial clinical trials in relatively small subject numbers have been conducted, there is no assurance that ongoing and future clinical trials will achieve efficacy and safety endpoints.
- **Regulatory risk**: The commercialisation of Scenesse in additional indications, as well as the commercialisation of additional pharmaceutical drugs, requires regulatory approval from agencies such as the FDA and EMA. Failure to satisfy regulatory agency requirements regarding clinical, CMC and other data would inhibit the ability of Clinuvel commercialise these drugs in the respective patient populations.
- **Commercial execution risk**: Clinuvel to date has directly commercialised its lead drug for patients with a single rare disease numbering ~5,000-10,000 patients. If Clinuvel are to directly commercialise pharmaceutical products in other disease settings, such as vitiligo and stroke, where there are far greater patient populations and different prescribing channels, we expect a significant expansion of infrastructure and personnel would be required.
- **Loss of exclusivity**: Due to granted patents and regulatory exclusivity periods, Clinuvel has commercial exclusivity for drugs containing afamelanotide. While it is uncertain if and when any competitors will develop generic afamelanotide products, we estimate generic entry would not be possible before ~FY28 in Europe and ~FY30 in the US, and possibly later if vitiligo becomes an approved indication. Competition from generics could impact sales through pricing pressure and market share of Scenesse.
- **Financial risk:** Clinuvel has been profitable for seven consecutive financial years and thereby generated a cash balance of A$157 million as of 30th June 2023 with no debt. We view Clinuvel as sufficiently financed to continue R&D activities for afamelanotide and other product candidates in the near-term. The company has publicly disclosed on several occasions the goal to internalise manufacturing capabilities and potentially in-license/acquire external pharmaceutical products. Clinuvel has significant cash at hand to execute this strategy and we have not included external funding in our forecasts.

- **Reimbursement risk**: Like most prescription drugs, Clinuvel depends on insurance providers to reimburse the cost of Scenesse across different jurisdictions. So far, Clinuvel has secured substantial insurance coverage across the US and Europe, however, has not yet achieved this in the UK (via NICE) and Australia (via the PBS). Continued sales in the US and EU are dependent on ongoing reimbursement, and geographic expansion is contingent on achieving reimbursement with additional national payors.

Board of Directors

Mr Willem Blijdorp - Non-executive Chair

Appointed Chair in 2019 and first appointed to the Board in Jan 2015, Mr Blijdorp established and was CEO of the B&S Group. In 2014, he received the Ernst & Young Entrepreneur of the Year award in the Netherlands and was runner-up in its EU awards. Mr Blijdorp is stepping down as Clinuvel Chairperson, effective as of 1st Jan 2024. He will remain a NED pending re-election at the 2023 AGM.

Dr Philippe Wolgen - CEO and Executive Director

Philippe Wolgen has served as Clinuvel CEO since 2005 and led the long-term strategy to develop and directly commercialise Scenesse for medical applications. Dr Wolgen holds an MBA from Columbia University, NY. Trained as a craniofacial surgeon, Dr Wolgen obtained his MD from the University of Utrecht, the Netherlands. Dr Wolgen's employment contract ends on 30 June 2025, thereafter the Board is conscious of the need for a new CEO.

Mrs Brenda Shanahan - Non-executive Director

Mrs Shanahan joined Clinuvel in 2007 and was Chair until 2010. Previously, Mrs Shanahan was a member of the ASX, partner of May Mellor Laing & Cruikshank and principal of Investment Consulting and worldwide partner at WM Mercer. She is currently a director of Phoslock Environmental Technologies (ASX: PET), DMP Asset Management, SG Hiscock, the Kimberly Foundation of Australia and the Aikenhead Centre for Medical Discovery. Mrs Shanahan previously been a director of St Vincent's Medical Research Institute, Challenger Limited (ASX: CGF), and Bell Financial Group (ASX: BFG) from 2012-2018.

Dr Karen Agersborg - Non-executive Director

Appointed in 2018, Dr Agersborg is a clinical endocrinologist, Board certified in both Internal Medicine and Endocrinology, Diabetes & Metabolism. Dr Agersbord previously worked in commercial sales at Wyeth. She is a Fellow of the American Association of Clinical Endocrinology and a Fellow of the American College of Osteopathic Internists.

Mrs Susan Smith - Non-executive Director

Appointed in 2019, Mrs Smith previously held CEO roles at the Princess Grace Hospital, London, the Portland Hospital for Women and Children, London, and the Independent Doctors Federation. She is currently Board Chair of the Evewell Group Ltd and Director of HCA Hope Fund UK. Mrs Smith manages an established consultancy business, providing advisory services to a range of healthcare organisations, investors and boards of directors.

Professor Jeffrey V. Rosenfeld - Non-executive Director

Appointed in 2019, Prof Rosenfeld is a neurosurgeon with experience in senior healthcare medical and research executive roles and a career in the Australian Army. Prof Rosenfeld was Director of Neurosurgery at the Alfred Hospital and Professor & Head of the Monash University Department of Surgery. He is currently a director of Vision for TBI Ltd and the Spirit of Australia Foundation.

Professor Sir Andrew Likierman - Non-executive Director

Appointed in 2022, Prof Likierman is Professor of Management Practice at the London Business School and was its Dean from 2009 to 2017. Andrew was a NED of Times Newspaper Holdings Ltd, the Bank of England, Monument Bank, Barclays Bank plc, Beazley plc, Applied Intellectual Capital plc, and Chair of the UK National Audit Office. He worked in the UK Cabinet Office and spent 11 years as Head of the UK Government Financial Management Service. Prof Likierman is resigning as Clinuvel NED "to focus on his various academic and consultancy activities", effective after the 2023 October AGM.

Key Management

Dr Dennis Wright - Chief Scientific Officer

Dr Wright spent over 17 years at CSL predominantly in regulatory affairs with nearly a decade as Regulatory Affairs Manager. Most recently he was Global Pharmacovigilance Manager and Regulatory Affairs Manager for the Mayne Pharma ANZ. He has a Pharmacy degree and post-graduate qualifications from University of Sydney and Health Economics qualifications from Monash University, Melbourne.

Mr Darren Keamy - CFO and Company Secretary

Mr Keamy is a qualified CPA who joined Clinuvel in 2005. Previously, Darren worked in management accounting and commercial roles in Amcor Limited for nine years. He also spent two years working in the UK, gaining experience in financial regulation and control within the banking and retail pharmaceutical industries.

Mr Lachlan Hay - Director of Global Operations

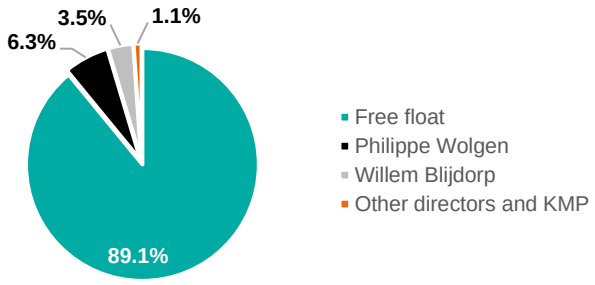
Mr Hay is General Manager of Clinuvel's European office, focused on the distribution of Scenesse in Europe. He has worked at Clinuvel for over a decade and previously held marketing communications roles in the not-for-profit sector in Australia. He holds a BA (Media & Communications) from the University of Melbourne, Australia, and a MA (International Relations) from the Freie Universität Berlin, Germany.

Figure 22 - Directors and KMP Interest

Name	Position	Ordinary Shares (#)	% Held
Philippe Wolgen	CEO & Director	3,122,247	6.32%
Willem Blijdorp	Non-executive chair	1,743,118	3.53%
Brenda Shanahan	Non-executive director	196,577	0.40%
Karen Agersborg	Non-executive director	5,500	0.01%
Susan Smith	Non-executive director	420	0.00%
Jeffrey Rosenfeld	Non-executive director	3,148	0.01%
Andrew Likierman	Non-executive director	1,000	0.00%
Dennis Wright	CSO	156,874	0.32%
Darren Keamy	CFO and Company Secretary	178,588	0.36%
Total shares held by Directors and KMP		**5,407,472**	**10.9%**
Free float		**44,002,866**	**89.1%**
Total shares on issue		49,410,338	100%

SOURCE: COMPANY DATA

Figure 23 - Register Composition



SOURCE: COMPANY DATA

Clinuvel Pharmaceuticals

as at 4th October 2023

Recommendation	Buy
Price	$14.12
Target (12 months)	$24.00

Table 1 - Financial summary

Profit & Loss (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Total sales	**65.7**	**78.3**	**93.4**	**109.4**	**127.9**
Growth (%)	*37%*	*19%*	*19%*	*17%*	*17%*
COGS	-6.8	-4.4	-6.5	-7.7	-9.0
Gross Profit	**59.0**	**73.9**	**86.8**	**101.8**	**119.0**
Gross margin	*90%*	*94%*	*93%*	*93%*	*93%*
Other income	0.8	0.8	0.0	0.0	0.0
Operating expenses	-25.2	-32.2	-34.8	-37.6	-40.6
EBITDA	**34.6**	**42.5**	**52.0**	**64.1**	**78.4**
Depreciation & amortisation	-0.8	-0.8	-0.8	-0.8	-0.8
EBIT	**33.9**	**41.7**	**51.2**	**63.3**	**77.6**
EBIT margin	*52%*	*53%*	*55%*	*58%*	*61%*
Net Interest (expense)/benefit	0.4	3.9	3.0	0.0	0.0
Profit before tax	**34.3**	**45.6**	**54.2**	**63.3**	**77.6**
Tax expense	-13.4	-15.0	-16.3	-19.0	-23.3
NPAT (pre abnormals)	**20.9**	**30.6**	**38.0**	**44.3**	**54.3**
Other comprehensive income/(loss)	-1.1	-1.5	0.0	0.0	0.0
Total comprehensive income/(loss)	**19.8**	**29.2**	**38.0**	**44.3**	**54.3**

Valuation Ratios (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Diluted EPS (cents)	40.3	59.1	73.3	85.6	104.8
EPS growth (%)	*-16%*	*47%*	*24%*	*17%*	*22%*
PE(x)	**35.0**	**23.9**	**19.3**	**16.5**	**13.5**
EV/EBITDA (x)	**15.8**	**12.9**	**10.5**	**8.6**	**7.0**
EV/Revenue (x)	8.3	7.0	5.9	5.0	4.3
NTA/share (cents)	291.0	391.7	466.9	554.9	663.5
Price/NTA (x)	4.9	3.6	3.0	2.5	2.1
Book value of equity/share (cents)	254.1	333.2	405.0	489.7	594.6
Price/Book value per share (x)	5.6	4.2	3.5	2.9	2.4
Dividend per share (cents)	4.0	5.0	5.0	5.0	5.0
Dividend payout ratio (%)	9.9%	8.5%	6.8%	5.8%	4.8%
Dividend yield (%)	0.3%	0.4%	0.4%	0.4%	0.4%
Franking (%)	0.0%	100.0%	100.0%	100.0%	100.0%

Cash Flow (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
EBITDA	34.6	42.5	52.0	64.1	78.4
Change in w orking capital	-4.4	0.8	-3.5	3.5	4.1
Gross operating cash flow	**39.0**	**41.6**	**55.6**	**60.6**	**74.3**
Income taxes paid	0.0	-7.7	-16.3	-19.0	-23.3
Net interest income/(payment)	0.2	2.7	3.0	0.0	0.0
Subsidies and grants received	0.6	0.3	0.0	0.0	0.0
Net operating cash flow	**39.9**	**36.9**	**42.3**	**41.6**	**51.0**
Payments for PPE & ROU	-0.4	-1.0	-1.0	-1.0	-1.0
Net investing cash flow	**-0.4**	**-1.0**	**-1.0**	**-1.0**	**-1.0**
Dividends paid	-1.2	-2.0	-2.5	-2.5	-2.5
Payment of lease liabilities	-0.3	-0.3	0.0	0.0	0.0
Net financing cash flow	**-1.5**	**-2.2**	**-2.5**	**-2.5**	**-2.5**
Net change in cash	**37.9**	**33.6**	**38.8**	**38.1**	**47.5**
Cash at start of period	82.7	121.5	156.8	195.6	233.8
Exchange rate impact	**0.9**	**1.7**	**0.0**	**0.0**	**0.0**
Cash at end of period	**121.5**	**156.8**	**195.6**	**233.8**	**281.3**

Performance Ratios	2022	2023	2024	2025	2026
Year Ending 30 June					
Gross margin	90%	94%	93%	93%	93%
EBITDA margin	53%	54%	56%	59%	61%
EBIT margin	52%	53%	55%	58%	61%
EBT margin	52%	58%	58%	58%	61%
NPAT margin	32%	39%	41%	41%	42%
Effective tax rate	-39%	-33%	-30%	-30%	-30%

Balance Sheet (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Cash and cash equivalents	121.5	156.8	195.6	233.8	281.3
Receivables	16.2	22.2	23.3	27.4	32.0
Inventories	1.8	9.5	6.5	7.7	9.0
Other current assets	1.0	1.1	1.1	1.1	1.1
PPE	1.5	2.0	2.1	2.2	2.3
Right-of-use assets	1.2	0.8	0.9	1.0	1.1
Intangibles	0.2	0.2	0.2	0.2	0.2
Deferred tax assets	0.5	1.1	1.1	1.1	1.1
Total assets	**143.9**	**193.7**	**230.9**	**274.4**	**328.0**
Payables	3.3	7.6	9.3	10.9	12.8
Income tax payables	7.3	16.1	16.1	16.1	16.1
Lease liabilities - current	0.3	0.3	0.3	0.3	0.3
Provisions - current	2.9	1.5	1.5	1.5	1.5
Deferred tax liabilities	3.6	2.8	2.8	2.8	2.8
Lease liabilities - non-current	0.9	0.7	0.7	0.7	0.7
Provisions - non-current	0.1	0.1	0.1	0.1	0.1
Total Liabilities	**18.4**	**29.1**	**30.8**	**32.4**	**34.2**
Net Assets	**125.6**	**164.6**	**200.1**	**242.0**	**293.8**
Issued capital	151.8	151.8	151.8	151.8	151.8
Reserves	12.1	22.6	22.6	22.6	22.6
Retained earnings/(accumulated losses)	-38.4	-9.8	25.7	67.6	119.4
Total equity	**125.6**	**164.6**	**200.1**	**242.0**	**293.8**

Leverage Ratios	FY22	FY23	FY24e	FY25e	FY26e
Net debt/(cash)	-121.5	-156.8	-195.6	-233.8	-281.3
Net debt/equity (x)	nm	nm	nm	nm	nm
Net debt/assets (x)	nm	nm	nm	nm	nm
Net debt/EBITDA (x)	nm	nm	nm	nm	nm

Revenue Analysis (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Scenesse (risk-adjusted)	65.7	78.3	93.1	108.9	126.9
Neuracthel (risk-adjusted)	0.0	0.0	0.0	0.0	0.0
Prenumbra (risk-adjusted)	0.0	0.0	0.0	0.0	0.0
PhotoCosmetics	0.0	0.0	0.3	0.5	1.0
Total revenue	65.7	78.3	93.4	109.4	127.9
Growth (%)	*nm*	*19%*	*19%*	*17%*	*17%*

Interim Results	1H23	2H23	1H24e	2H24e
Revenue	29.4	49.0	35.0	58.4
EBITDA	13.6	28.8	14.3	37.7
NPAT (pre abnormals)	11.4	19.2	15.4	22.5

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

Buy: Expect >15% total return on a 12 month view. For stocks regarded as 'Speculative' a return of >30% is expected.

Hold: Expect total return between -5% and 15% on a 12 month view

Sell: Expect <-5% total return on a 12 month view

Speculative Investments are either start-up enterprises with nil or only prospective operations or recently commenced operations with only forecast cash flows, or companies that have commenced operations or have been in operation for some time but have only forecast cash flows and/or a stressed balance sheet.

Such investments may carry an exceptionally high level of capital risk and volatility of returns.

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