PARMANTIER & CIE.

UPDATE "PHARMA/BIOTECH"
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BUY (Buy) | Share price potential+ 85%

Target price AU$ 22,00- (19.27)
Share price* AU$ 11.87

*Closing price ASX, Sydney (07/03/2025)

CLINUVEL Pharmaceuticals

ASX: CUV - ADR Level1: CLVLY

Frankfurt/M stock exchange: UR9 - ISIN: AU 000000CUV3 - WKN: AOJEGY

H1/25 with another record result - more speed + higher opportunities

CLINUVEL Pharmaceuticals Ltd (CLINUVEL or CUV for short) has delivered **convincing and record-high figures for H1/FY25**, **exceeding market expectations in our view.** High revenue growth and controlled cost development have expanded **H1/FY25-EPS by 27.4% to AU$28.1 cents**. At the same time, the company is investing heavily in future growth and liquidity is increasing.

We are adjusting our estimate and our target price from 19,27 to AU$ 22,00. We **expect a strong newsflow** (on EPP, CUV105, CUV107) and reiterate our **BUY recommendation**.

The aim is to accelerate both development and revenue generation. Under the **new strategy** - with a focus on the development of three advanced clinical projects (vitiligo; ACTH, VP) - we believe the opportunity **for a leap in growth is increasing,** triggered by the targeted SCENESSE approval® (possibly in 2028) for the treatment of the large vitiligo patient group. The US national market will play a decisive role.

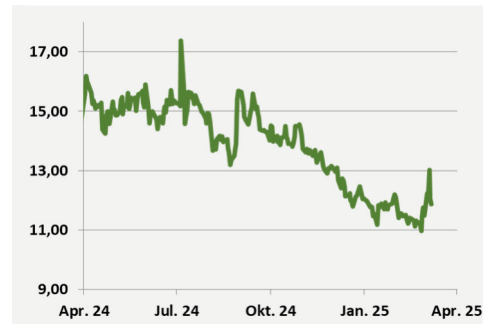
The launch of **"PhotoCosmetics"** (non-Rx; OTC) will be an important step forward to establish a non-Rx revenue stream. In our opinion, **CUV is leading the emerging industry trend** towards science-based **cosmetic** products. The market launch of CYACÊLLE Radiant is now planned for later CY**2025**. Improved visibility in the user groups is an explicit objective and includes the capital market (supplemented by efficiency measures).

Despite the successes in the operating business and in focusing the business model, the **Board of Directors is looking for a new CEO**.

PCR valuation: Low valuation; Risks are product and competition related.

FY 30.6.; in AU$ m	(23-27e)	2023	2024	2025e	2026e	2027e
Turnover	13,1%	78,32	88,18	99,40	112,15	128,35
EBITDA	11,2%	42,46	44,50	51,23	53,44	65,01
EBITDA margin, %		54,2%	50,5%	51,5%	47,6%	50,6%
EBIT	11,1%	41,67	43,35	49,83	51,99	63,44
EBIT margin, %		53,2%	49,2%	50,1%	46,4%	49,4%
Consolidated earnings	13,0%	30,60	35,64	40,33	41,86	49,94
EPS, in AU$	12,9%	0,61	0,71	0,80	0,84	1,00
Dividend per share, in cent	25,6%	5	5	6	8	12
EV/Sales		10,72	7,30	4,14	3,67	3,20
EV/EBITDA		19,8	14,5	8,0	7,7	6,3
P/E RATIO		39,5	23,1	14,8	14,2	11,9

Source: Company data, PCR



SHAREHOLDER STRUCTURE

Free Float	51.80%
Inst. Investors	33,0%
Dr. Ph. Wolgen (CEO)	6,8%
Ender 1, LLC	5.2%
Martin Hess	2,0%
Emilino Pty Ltd	1,2%

BASIC DATA SHARE

Ticker (Bloomberg)	CUV:AU
Number of shares (in millions)	50,1
Free float (in %)	51,8%
Market capitalisation (in AU$m)	594,3
Trading volume (Ø-100 days; in k AU$ m)	1,7
52-week high (in AU$)	17,71
52-week low (in AU$)	10,89

FINANCIAL CALENDAR

AGM	August 2025

ANALYSTS

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H1/25 - Record figures - Adjustment of expectations

CLINUVEL continues to expand. **Total revenue in the half-year period increased by AU$ 7.6 million (+21.1% year-on-year)** to a new **record of AU$ 43.3 million**. **Earnings per share (basic) rose by 27.4% to 28.1 cents per share at the same time**. Business performance in H1/25 was thus **better than market expectations** and also exceeded our forecast. However, a significantly improved, neutral result - from the areas of finance and currency effects - had overstated the improvement in operating earnings. **Our forecast and the market expectation will have to be adjusted.** Management is also **confident of achieving a "strong result" for FY25**. As in the past, no further guidance for FY25 will be published.

Commercial sales (+ 9.2% to AU$ 32.6 million) and reimbursements under the Special Access Scheme (AU$ 3.0 million compared to AU$ 2.4 million) once again grew at a double-digit rate and reached **a new historic high** of **AU$ 35.6 million (+ 10.5% compared to the previous year).** This **successful increase in sales** is due to the rise in the number of patients, the increase in treatment doses per patient and the growth in the number of prescribing doctors.

The **other income item** benefited from (unrealised) currency gains (AU$ 3.03 million, previous year: AU$ 0.19 million). The very **comfortable position in cash reserves** was once again increased despite the rise in operating expenses (+7.8% compared to the previous year to AU$ 198.2 million). The company **benefited from high interest income** from term deposits, with income increasing by 26.1% year-on-year to **AU$ 4.6 million** (AU$ 3.7 million). These **two income categories** together delivered AU$ 7.6 million, which is AU$ 4.1 million more than 12 months ago (+117% YoY).

Total expenses rose to AU$ 21.4 million in the half-year (+2.0% compared to the previous year). Operating expenses increased in **line with the Group's expansion initiatives,** as evidenced by the increase in personnel costs and the significant rise in clinical and non-clinical development costs. In contrast, non-cash expenses, in particular non-cash share-based payments, fell sharply.

In detail:

Expenditure on clinical and non-clinical development totalled **AU$ 2.8 million, an increase of 277.4 % on the previous year**, reflecting the strategic focus on the further development of various clinical programmes. In the reporting period, it was in particular the recruitment of the vitiligo study CUV105 that caused the sharp rise in costs. It is expected **that the costs for clinical trials will continue to rise in the future** as patients progress through the vitiligo studies (CUV105 and CUV107) and clinical studies in other indications.

he company is well into its **expansion phase in North America.** The number of trained and approved specialty centres in North America has now reached 93 and is not far from the target of 120 centres to be reached this year. The **network of centres is intended both for the treatment of EPP patients and**, in due course, for the treatment of **vitiligo patients** while clinical trials are ongoing and regulatory submissions are being made**.**

Personnel costs rose to AU$ 10.8 million or 34% compared to the previous year, which is primarily due to an **increase in the number of employees (+11.5%)**, particularly in the clinical and regulatory teams. The majority of staff are employed outside Australia. In this context, it is important to note that

the very high proportion of foreign currency income also acts as a natural hedge against **the weaker Australian dollar.**

The Group's **administrative costs (legal, IP)** fell by 37.9% to AU$ 0.5 million following the completion of the larger projects in the comparative period. **Sales costs in the narrower sense grew in line with the increase in revenue.** Regulatory costs (EMA, FDA) were added, so that the amount in this expense category **rose by 24.7% to AU$ 1.7 million. Material and ancillary costs totalled an exceptionally low AU$ 0.13 million, which** corresponds to **a decrease of -96.8%** compared to the previous year. In addition to timing aspects, improvements in the production process had a positive impact. **Expenditure on communication, branding and marketing (CBM)** totalled **AU$** 0.59 million, a decrease of 10.1% compared to the previous year. Expenditure in this category is expected to grow noticeably in the coming months. An important milestone will be the presence at the annual meeting of the American Academy of Dermatology (AAD) in Orlando (7-11 March).

Non-cash expenses for **share-based payments fell** significantly by AU$ 4.6 million (-82% compared to the previous year) **to AU$ 1.0 million**. The share option programme from November 2023 had expired and a new programme, which is to cover a significantly larger number of employees in future, is to be launched later in the year.

For **H1/FY24-25, the company reported a pre-tax profit of AU$ 21.9 million, an increase of AU$ 7.1 million or 48.1 % compared to the previous year**. The profit after tax of AU$ 14.1 million represents an increase of AU$ 3.1 million or 28.7 % compared to the previous year.

With this **28.7%** increase in **NPAT, earnings per share (basic) also increased from 22.1 cents per share to 28.1 cents per share**. The weighted average number of ordinary shares in issue increased from 49.546711 million shares in FY2023 to 50.067595 million shares in the current period.

Maintaining a solid balance sheet - including freedom from debt - remains a strategic priority for CLINUVEL. This is reflected in an increase in total assets of AU$ 14.2 million to AU$ 217.3 million, which ultimately **led to** a further improvement in the net asset position.

The **operating cash inflows** were primarily generated by global revenues from SCENESSE® sales, which **totalled AU$ 49.8 million, an increase of 14 % compared to AU$ 43.6 million in the previous year**

PCR estimates for FY2025 - FY2027

We expect commercial sales for the current FY25 to be AU$99.4m (+13% YoY), not taking into account **the upcoming EMA decisions on the** use of SCENESSE® in EPP patients (label adjustment, adolescent patient groups).

Including other income and interest income, "total income" will initially increase by 13% YoY and then by 14% YoY according to our planning in the detailed planning phase **FY2026 - FY2027.** As a precautionary measure, we plan for a declining interest rate level for term deposits. The increase in net liquidity will initially lead to an absolute increase in interest income (FY2024: AU$7.33m) As a result, we expect the liquidity position to decline.

In our opinion, the significance of **personnel costs is likely to increase over the three-year period in line with the trend in R&D expenditure**

FY25 Catalysts - initial impetus for SCENESSE® for the treatment of EPP in the EU

In our opinion, the next catalyst for growth be the decision by the EMA committees (PRAC) on a **change in authorisation**. The company recently expressed optimism regarding the EMA's decision in the coming months. CLINUVEL **is at an advanced stage** of discussions with the European Medicines Agency (EMA) to **increase** the recommended **maximum number of doses** per year of its drug SCENESSE® (afamelanotide 16 mg) for adult patients with erythropoietic protoporphyria (EPP) **from the current four to up to six subcutaneous doses per year** (+50%). We estimate the expected **additional sales** to be in **the mid double-digit million euro range per year.**

Also pending is a decision by the EMA on an application by CLINUVEL **for an extension of the marketing authorisation** to make **SCENESSE®** available **for additional EPP patient groups** (**adolescents aged 15-17)**. We estimate the number of affected adolescent patients in Europe to be around 150, which **would correspond** to a **total addressable market "adolescent EPP" of around AU$15m p.a. (>€9m). The EMA decision is still pending and is expected for CY 2025 (AU$6.0m p.a. (= €3.6m))**. The CUV052 trial will also **support** the extension of the **US approval** for 12-17 year olds in the US.

CLINUVEL has an integrated business model. The group of companies **is debt-free and has been operating profitably for over eight years. Despite the upcoming adjustments to the business model, this should also apply to the future.** Among other things, this will also **redefine** the **tasks of the Executive Board**, especially as the **US national market is currently growing in importance.** The planned expansion of the product portfolio for the treatment of VITILIGO will initially have its regional focus in **North America**. CLINUVEL is testing (CUV105-Phase III) the first systemic therapy for vitiligo that offers comprehensive repigmentation without suppressing the immune system. **Around 120 treatment centres are to be set up** by the end of **2025.** This will allow EPP patients to be treated almost nationwide in the USA - and in Canada. This network would not only reach many of the **estimated 1,300 EPP patients in the USA** (approx. 333 million inhabitants), **but would also** be able to admit and treat **around 6,000 vitiligo patients per year.** The presence of a "Pavilion of Photomedicine" at the forthcoming **AAD annual congress in Orlando, Florida, is therefore of great importance in our opinion.**

An important task was and is to **make** the activities (spread over two continents) **scalable** for **more complex development programmes and new projects**. To this end, the organisation was adapted and appropriate software implemented. The study centres were put in a position to look after larger groups of patients and test subjects (e.g. in the vitiligo studies). At the same time, **administrative processes** were **optimised** so that the necessary infrastructure for the treatment of vitiligo patients will be available at a later date. **Important functions** (R&D, regulatory affairs, sales and distribution, branding) of the company are **carried out "in-house"** as far as possible and not outsourced to third parties. **In future, important production steps will also be organised internally**, which is only logical in view of the targeted approvals and the associated strong growth in product volumes.

Objectives	Catalyts 2025
Growing commercial distribution of SCENESSE® for EPP	Engagement EMA on CUV052 and adolescent EPP patient use of SCENESSE® EMA decision on SCENESSE® dosage for EPP patients Expand to 120 North American Speciality Centers Health Canada decision on marketing autorisation, SCENESSE® for EPP patients
Developing melanocortins	**Vitiligo** Complete recruitment CUV105 study commence study CUV107 **Variegate Porphyria (VP)** Regulatory feedback and commence CUV053 **Stroke** CUV803 results **NEURACTHEL® (ACTH)** manufacturing update
Increasing visibility	American Academy of Dermatology (AAD) Meeting CYACÉLLE next generation product launch
Global IR engagement	FY2025 result and non-deal roadshows Anual General Meeting

Source: Company data; PCR - 07.03.25

In addition to the development of pharmaceuticals, the launch of a range of non-pharmaceutical consumer products (non-Rx; OTC), known as "**PhotoCosmetics",** is being **driven forward**. CLINUVEL sees itself as the **world's first company** to develop and commercialise a technology that **activates melanin production in the skin without sun exposure**. This means that the body's natural tanning mechanism is replicated, while the **health risks** associated with ultraviolet rays **are avoided**.

Following the pilot launch of the polychromatic light-stabilising emulsions **CYACÊLLE and CYACÊLLE Radiant, the global market launch is now planned for later CY2025.** Here, too, the US market is at the top of the agenda. The launch of the **second product line** (CLINUVEL Preserve - Assisted DNA Repair) and the **third product line** (CLINUVEL Bronze for self-tanners) is expected to follow. They are planned **for 2026**. **We continue to expect the CYACÊLLE product line to make a larger contribution to sales from CY2027**

INVESTMENT THESES

The existing SCENESSE® business can **generally expect sales growth and high margins in the near future**, as no alternative EPP treatments are expected any time soon, as developments among market competitors show. The **approval (~FY28) of SCENESSE®** for the treatment of **vitiligo** will make the US national market the largest customer region in the future.

This **quantum leap in the company's history** will noticeably **change** CLINUVEL in many respects**, for which the essential course has been set. In this critical** phase**, the Supervisory Board is looking for a new CEO (CN 28 February 2025)**, which in our view needs to be carefully managed.

In the foreseeable future, the decisions of the EU regulatory authorities on the planned expansion of the use of **SCENESSE®** (to adolescent EPP patients) in Europe and the EMA-PRAC decision on the harmonisation of the label (EPP treatment frequency) could provide additional growth and earnings impetus.

Total revenues have grown at an 8-year CAGR (2017-24) of 38% to AU$95m in FY24. CUV has been profitable for eight consecutive years, with an EBIT margin of between c.48-52% in the last three financial years. The **H1/FY25 figures** now **presented support this target**.

The recent focussing of this development work on the more advanced projects **ultimately increases their market opportunities**. However, the opportunities of the early projects will be suspended for the time being and the accelerated development work will utilise the greater, more immediate potential.

In principle, the investment risk decreases with the increasing breadth of the business model. This also applies in the context of the **strategy adjustment implemented** at the turn of the year 2024/25**.** CLINUVEL has several development lines that should accelerate growth in the medium term. Systemic photoprotection (EPP) and skin repigmentation (vitiligo) remain central. The **approval (~FY28) of SCENESSE®** for the treatment of **vitiligo and the market launch (~FY28)** of the generic **NEURACTHEL® (ACTH)** are likely to be the biggest potential growth drivers.

The **high internal financing power** will now be **concentrated on three core projects** so that, in our estimation, **no external sources of financing** will need to be utilised in the foreseeable future. On the other hand, we believe the Board is likely to organise **the appropriation of profits** (special dividends, share buyback) more sparingly during this concentrated investment phase. **IR work was intensified in 2024** with roadshows in Switzerland and Germany and the expansion of activities in the USA.

The defensive core business and the strong balance sheet (no financial debt) justify an EV/EBIT premium. However, the EV/EBIT valuation (7.9x (26e)) **is below the historical average** (discount to competitors: a good 30%)

The **strong operating performance in H1/FY25** and the recent focussing of the strategy have **increased the attractiveness of the share** in our view. We expect **market expectations to be adjusted**. Furthermore, we see a good chance that the upcoming EMA decisions on **SCENESSE®** for EPP treatment can provide positive impetus.

We reiterate the BUY recommendation for the shares of CLINUVEL Pharmaceuticals Ltd.

KEY FINANCIAL FIGURES

P&L (in AU$m)	2022	2023	2024	2025e	2026e	2027e
Total Revenues	**65,722**	**78,321**	**88,178**	**99,400**	**112,150**	**128,350**
Total interest income	0,444	3,906	7,325	7,522	7,551	7,585
Total other income (loss)	0,821	0,763	-0,197	0,436	0,441	0,476
Total revenues, interest and other income	**66,988**	**82,990**	**95,306**	**107,359**	**120,142**	**136,411**
Expenses						
Personnel-related	-11,591	-13,577	-18,918	-22,168	-24,868	-28,575
Share-based Payments	-6,121	-8,990	-6,107	-1,346	-6,169	-7,743
Materials and related expenses	-5,402	-12,063	-5,201	-6,613	-8,299	-9,336
Clinical and non-clinical dev.	-1,233	-1,268	-2,348	-4,941	-6,103	-5,640
Finance, corporate, general, legal, insurance, IP	-3,422	-4,516	-6,197	-7,309	-6,652	-5,639
Commercial distr.; Communication branding and marketing	-2,786	-3,895	-5,819	-7,326	-8,304	-7,678
Depreciation and amortisation	-0,758	-0,789	-1,142	-1,398	-1,451	-1,567
Changes in inventories	-1,355	7,688	1,107	1,100	1,241	0,792
Total expenses	**-32,667**	**-37,412**	**-44,627**	**-50,002**	**-60,605**	**-65,387**
Profit before income tax	34,321	45,579	50,679	57,357	59,537	71,024
Income tax expense	**-13,442**	**-14,974**	**-15,043**	**-17,025**	**-17,672**	**-21,082**
Operation profit after income tax	20,878	30,605	35,636	40,332	41,865	49,943
Net profit for the year	**20,878**	**30,605**	**35,636**	**40,332**	**41,865**	**49,943**
Exchange differences foreign exchange translation of foreign operations	-1,057	-1,454	0,139	0,000	0,000	0,000
Total comprehensive income for the period	**19,821**	**29,150**	**35,775**	**40,332**	**41,865**	**49,943**
Number of shares (millions)	50,100	49,830	50,130	50,130	50,130	50,130
Diluted number of shares (millions)	50,100	49,830	50,130	50,130	50,130	50,130
Basic earnings per share - cents per share	**40**	**58**	**71**	**80**	**84**	**100**
Diluted earnings per share - cents per share	**40**	**58**	**71**	**80**	**84**	**100**
Dividend per share - cents per share	**3**	**5**	**5**	**6**	**8**	**12**

Source: Company (historical data)/PCR (forecast)

Cash flow statement (in million AU$s)	2022	2023	2024	2025e	2026e	2027e
Cash flow from operating activities	39,87	36,91	37,05	37,94	39,01	46,04
Cash flow from investing activities	-0,434	-1,028	-5,576	-5,520	-5,520	-6,318
Cash flow from financing activities	-1,504	-2,240	-3,572	-2,507	-2,826	-4,189
Change in cash and cash equivalents	**37,934**	**33,644**	**27,906**	**29,917**	**30,667**	**35,537**
Cash and cash equiv. end of the period	121,509	156,814	183,868	213,785	244,452	279,989

Source: Company information (history)/PCR (forecast)

Balance sheet (in million AU$s)	2022	2023	2024	2025e	2026e	2027e
Fixed assets	***2,885***	***3,036***	***7,905***	***12,028***	***16,097***	***20,848***
Intangible assets	1,345	1,018	0,923	0,923	0,923	0,923
Property, plant and equipment	1,541	2,018	6,982	11,105	15,174	19,925
Financial assets	0,000	0,000	0,000	0,000	0,000	0,000
Current assets	***139,543***	***188,548***	***220,733***	***255,342***	***291,339***	***333,648***
Inventories	1,832	9,519	10,627	11,979	13,516	15,468
Trade receivables	16,202	22,215	26,238	29,577	33,371	38,192
Other receivables	0,000	0,000	0,000	0,000	0,000	0,000
Cash and securities	121,509	156,814	183,868	213,785	244,452	279,989
Other assets	1,521	2,130	2,485	2,485	2,485	2,485
Total assets	**143,950**	**193,714**	**231,124**	**269,854**	**309,921**	**356,981**
Shareholders' equity	***125,559***	***164,631***	***203,011***	***240,837***	***279,876***	***325,630***
Reserves	125,559	164,631	203,011	240,837	279,876	325,630
Minority interests	0,000	0,000	0,000	0,000	0,000	0,000
Accrued liabilities	***2,961***	***1,581***	***2,046***	***2,046***	***2,046***	***2,046***
Accounts payable	***11,814***	***24,744***	***23,840***	***24,745***	***25,773***	***27,079***
Interest-bearing liabilities	0,000	0,000	0,000	0,000	0,000	0,000
Liabilities from trade payables	3,278	7,650	7,109	8,014	9,042	10,348
Other non-interest-bearing liabilities	8,536	17,094	16,731	16,731	16,731	16,731
Other liabilities Other liabilities	***3,615***	***2,758***	***2,226***	***2,226***	***2,226***	***2,226***
Total liabilities	**143,950**	**193,714**	**231,124**	**269,854**	**309,921**	**356,981**

Source: Company information (history)/PCR (forecast)

Overview of key figures	2022	2023	2024	2025e	2026e	2027e
Key valuation figures						
EV/Sales	19,50	10,72	7,30	4,14	3,67	3,20
EV/EBITDA	36,99	19,78	14,46	8,03	7,69	6,33
EV/EBIT	37,82	20,15	14,84	8,25	7,91	6,48
P/E RATIO	72,40	39,48	23,12	14,75	14,21	11,91
Price/book value	11,172	6,054	4,074	2,471	2,126	1,827
Profitability ratios in %						
Gross margin	91,0%	95,4%	95,1%	94,9%	94,1%	93,7%
EBITDA margin	52,7%	54,2%	50,5%	51,5%	47,6%	50,6%
EBIT margin	51,5%	53,2%	49,2%	50,1%	46,4%	49,4%
Pre-tax margin	51,5%	53,2%	57,5%	57,7%	53,1%	55,3%
Net margin	29,5%	32,2%	40,6%	40,6%	37,3%	38,9%
ROE	30,9%	17,4%	19,5%	18,2%	16,1%	16,5%
Key productivity figures						
Turnover/employee (in AU$ thousand)	566,57	824,43	899,78	879,65	862,69	861,41
Net revenue/employee (in AU$ thousand)	180	322	364	357	322	335
Number of employees	116	95	98	113	130	149
Key financial figures						
Equity ratio	87,2%	85,0%	87,8%	89,2%	90,3%	91,2%
Dividend yield	0,1%	0,3%	0,3%	0,5%	0,7%	1,0%
Working capital/sales (in %)	22,5%	30,8%	33,7%	33,7%	33,7%	33,7%
Depreciation/sales (in %)	1,2%	1,0%	1,3%	1,4%	1,3%	1,2%
Tax rate (in %)	39,2%	32,9%	29,7%	29,7%	29,7%	29,7%

Source: PCR

DISCLAIMER

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Company	Analysts	Date	Recommendation / Target price
CLINUVEL Pharmaceuticals Ltd.	T.Schiessle; D.Großjohann	09.09.2024	Buy/AU$ 26.10
CLINUVEL Pharmaceuticals Ltd.	T.Schiessle; D.Großjohann	10.02.2025	Buy/AU$ 19.27
CLINUVEL Pharmaceuticals Ltd.	T.Schiessle; D.Großjohann	07.03.2025	Buy/AU$ 22.00

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