BUY (Buy) Price potential+134%

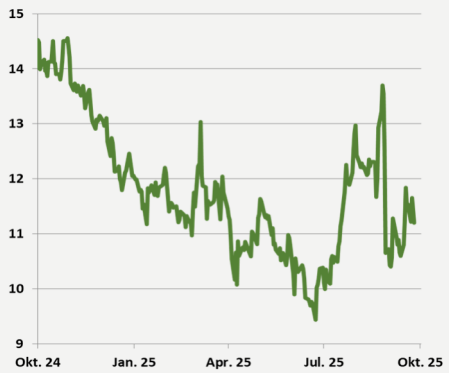
Target price AU$ 26.50 (22.00)
Share price* AU$ 11.30

*Closing price ASX, Sydney (26.09.2025)

CLINUVEL Pharmaceuticals Limited

ASX: CUV - ADR Level 1: CLVLY –
Frankfurt Stock Exchange: UR9 - ISIN: AU 000000CUV3 - WKN: AOJEGY

FY 2026 with sales boost - more focus on the US – with own US-production no trouble with US-tariffs - uplisting Nasdaq at the right time



Good news for CLINUVEL: **the recent EMA-PRAC decision** on label harmonization **brings sales boost from FY 26 onwards**, in our opinion. The consequence is a noticeable **increase in PCR estimates beyond market consensus**, with a rising **target price.** At the right time, additional investor groups will thus be targeted on the world's largest biotech exchange through the planned **uplisting of ADRs to Level II on Nasdaq** (till end of CY 25). Improved visibility on capital markets is an explicit objective among user and physician groups too. Following the success in spring 2025, participation in **the AAD Annual Meeting in Denver in March 2026** is **planned. Newsflow momentum will remain high,** when EMA approval extension for SCENESSE® (EPP) for adolescent patients is expected before end of CY25.

The **strategy** communicated since the turn of the year 24/25 – **to give high priority to** the targeted North American approval for the indication **vitiligo, followed by PRÉNUMBRA® and NEURACTHEL® – opens up** the opportunity for a even bigger **leap in growth** in our opinion**.**
Work on the approval (~FY28) of SCENESSE® for the treatment **of vitiligo** is progressing according to plan – with CUV104 (helpful NB-UVB required), CUV105 (first results in H2/26), CUV107.
The company's presence in **the US market**, which is **very important** for this, is being consistently expanded (to 120 treatment centres in North America), including through M&A**.** It will **be available for the treatment** of **both EPP and vitiligo patients;** which saves costs and gains time.
Until the end of his current term of office (30 June 2026), **CEO Dr Wolgen** will **focus on the US market**. Under his leadership, regional and product diversification has been implemented, thereby reducing business risk.
The search for a successor to the CEO has begun.
The completed **FY24/25 was** characterised **by cost discipline and renewed profitable growth** – with a dividend payment of 5.0 AU$ cents/share.
PCR rating: Low rating, product and competitive risks.

FY 30.6.; in AU$ m	(24-28e)	2024	2025	2026e	2027e	2028e
Turnover	17,3%	88,18	95,02	113,75	132,65	167,15
EBITDA	24,3%	44,50	43,30	59,14	75,67	106,24
EBITDA margin, %		50,5%	45,6%	52,0%	57,0%	63,6%
EBIT	24,6%	43,35	42,12	57,87	74,19	104,37
EBIT margin, %		49,2%	44,3%	50,9%	55,9%	62,4%
Consolidated earnings	20,8%	35,64	36,17	48,45	61,07	75,97
EPS, in AU$	20,8%	0,71	0,72	0,97	1,22	1,52
Dividend per share, in cent	20,7%	5	5	7	9	11
EV/Sales		7,30	4,50	3,01	2,58	2,05
EV/EBITDA		14,5	9,9	5,8	4,5	3,2
P/E RATIO		23,1	19,3	11,7	9,3	7,5

Source: Company data, PCR

SHAREHOLDER STRUCTURE

Free Float	79,5%
Inst. Investors	49,0%
Dr. Ph. Wolgen (CEO)	6,8%
Ender 1, LLC	5,2%
Martin Hess	2,0%
Emilino Pty Ltd	1,2%

BASIC SHARE DATA

Ticker (Bloomberg)	CUV:AU
Number of shares (in millions)	50,1
Free float (in %)	79,5%
Market capitalisation (in AU$m)	566,4
Trading volume (Ø-100 days; in k AU$ m)	1.370
52-week high (in AU$)	14,96
52-week low (in AU$)	9,41

FINANCIAL CALENDAR

AGM	17.10.2025

ANALYSTS

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INVESTMENT THESES

CLINUVEL (CUV) is a pioneer in "photomedicine" and is benefiting from rapidly growing awareness of light-related health risks. CUV is one of the few biopharmaceutical companies that is sustainably **profitable**. The company **markets** its **drugs independently and highly profitably** in the US and the EU, enabling it to **pay dividends**. CLINUVEL markets SCENESSE®, the only approved treatment for patients with erythropoietic protoporphyria (EPP), a rare, light-induced hereditary disease.

The existing SCENESSE® business can **generally expect revenue growth and high margins in the near future**, as no alternative EPP treatments are expected anytime soon, as developments among market competitors show. The **approval (~FY28) of SCENESSE®** for the treatment of **vitiligo is likely to trigger a quantum leap in revenue and earnings.**

Thanks to US production and logistics, **CUV is not affected by the impending 100% US tariffs**.

The **EMA-PRAC decision on the harmonization of the SCENESSE® label** was made in September 2025 and definitely **has a positive impact** on our PCR planning. The decision of the EU regulatory authorities regarding the planned extension of the use of SCENESSE® (EPP) to adolescent patients in Europe (expected by the end of CY 2025) **could provide an additional growth impetus.**

CUV is an **atypical biotech company**. It has been **profitable** for the ninth consecutive year**,** with an EBIT margin of between approximately 46-48% in the last three financial years**. A dividend was paid in September 2025 for an eighth consecutive year**. The company intends **to grow** at a **similar rate** in the future and is developing a limited number of additional drugs and cosmetics for this purpose.

In addition to regulatory changes in Europe, we see the uplisting on Nasdaq as the next growth catalyst, which **is coming at just the right time**. **IR work will be further intensified**, which will significantly improve visibility on the capital market. More and more shareholders come from the USA.; visibility and communication there will be significantly expanded.

To this end, the **Nasdaq listing of ADRs will be raised to Level II** by the end of 2025**.** Regulatory requirements for the company are increasing, making additional investor groups – especially the **important institutional investors** – in the United States accessible. For high-growth biotech companies – with their many cross-border activities – there is usually no way around the Nasdaq, if only because of the market liquidity and the specialized investor base. The total market capitalisation of the **Nasdaq Biotechnology™ Index (NBI)** with its over 250 stocks is approximately **US$1,220 billion, with heavyweights including well-known names such as Amgen, Gilead Sciences, Regeneron Pharma and Vertex Pharmaceutical** (NBI).

A capital increase is not planned in this context (CN dated 22 August 2025). The primary listing on the Australian Securities Exchange (ASX) will remain in place.

In principle, the investment risk decreases as the business model broadens. This also applies in the context of **the strategy adjustment implemented in FY 2025.** CLINUVEL has several lines of development that are expected to accelerate growth in the medium term. Systemic photoprotection (EPP) and skin repigmentation (vitiligo) remain central. The **approval (~FY 2028) of SCENESSE®** for the treatment of **vitiligo and the US market launch (~FY 2028)** of the generic drug **NEURACTHEL® (ACTH)**

are likely to be the biggest potential growth drivers (**US filing CY 2026e)**. The company's strategy, which was adjusted at the turn of 2024, also focuses on these two projects.

The opportunities for the early projects are being put on hold for the time being, and the accelerated development work will exploit the greater, more immediate potential. Focusing development work on the more advanced projects **increases their market opportunities**.

Recruitment of patients (n=210) for the **CUV105 study (SCENESSE®** for the treatment of **vitiligo)** was completed in May 2025; **initial results** are **expected in H2/26** after 5 months of treatment and 6 months of follow-up**. The CUV107** pivotal **study** is scheduled to begin in CY Q4/25/Q1/26.

The direct sales model is also central to the launch of the 'PhotoCosmetic' product lines, which target the **huge luxury skincare market** (CY 2027e: US$ 260 billion). The recently launched CYACÊLLE plays an important — synergistic — role due to its high level of brand recognition. **By the end of CY 2026, two more OTC skincare series ('M-Line') are expected to follow**, allowing the full impact on the brand and the income statement **to unfold**.

The **high level of internal financing power** is now **being concentrated on three core projects**, so that, in our opinion, **no external sources of financing** will be required in the foreseeable future. On the other hand, the Board of Directors intends to be more cautious in **its use of profits** (special dividends, share buybacks) during this concentrated investment phase.

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

Our valuation is based on a **75:25** weighted average of (1) risk-adjusted DCF (AU$ 31.39, previously AU$ 23.00) and (2) EV/EBIT (26e) **AU$ 10.08.** The risk/reward ratio has recently improved, which is why we are raising the target price **of AU$ 22.00 to AU$ 26.50.**

The market is primarily focused on the **risk-reward ratio of the planned approval of SCENESSE®** for the treatment of vitiligo (~FY28) as the biggest potential growth driver. We currently estimate the probability of approval (**Phase III CUV105 study first results in H2/2026)** at 61.2% (i.e. NPV on the US market: AU$ ~960 m.). We currently value the SCENESSE® franchise **at an NPV of ~ AU$ 950 m.** Considering the track record and probability of success**, CUV shares** are **significantly undervalued from an analytical perspective.**

In the near term, the pending EMA decisions on **SCENESSE®** (EPP) could, in our opinion, **trigger** growth momentum and **upgrades in the capital market**.

In our opinion, the strategic focus and risk reduction have **increased the attractiveness of the share**. The significant (+10-20%) increase in peer valuation points in the same direction. Measures to improve transparency, such as the Nasdaq uplisting of ADRs to Level II, are welcomed and should, in our opinion, be implemented swiftly.

We confirm our BUY recommendation for CLINUVEL Pharmaceuticals Ltd. shares.

STRATEGY

Focus and acceleration

The leading product is the prescription implant SCENESSE® (afamelanotide 16 mg). It is approved for commercial distribution in Europe, the US, Israel and Australia as the world's first systemic photoprotective agent for the prevention of phototoxicity (anaphylactoid reactions and burns) **in adult patients with erythropoietic protoporphyria (EPP)**. Reimbursement is provided through special access programmes (e.g. Switzerland, Canada) in countries where **regulatory authorities have not approved the product for marketing**.

CLINUVEL has an integrated business model. The group **is debt-free and has been operating profitably for over nine years.** It is noteworthy that the company only had to invest AU$150 m. in the development of SCENESSE for EPP, a fraction of the industry norm. **Key functions (**R&D, regulatory affairs, sales and distribution, branding) of the company are **carried out** "**in-house"** as far as possible and are not outsourced to third parties. **In future, key production steps will also be organised internally,** which is only logical given the targeted approvals and the associated strong growth in product volumes. According to reports, the planned production department will develop product formulations for transdermal/parenteral systems.

The development pipeline **has been focused on the three advanced clinical projects** with afamelanotide (SCENESSE®) for **vitiligo; ACTH, EPP and VP** from a previous total of **nine projects, six of which were in clinical development**. The decision was based on the highest prospects of success and the fastest routes to regulatory and commercial success. For this reason, the generic drug NEURACTHEL® (**autoimmune and CNS diseases)** will also **be further developed.**

	Catalysts and Calendar	CY 2025 - CY 2026
Commercial growth	**SCENESSE® EMA decision dosage expansion adults**	**23. Sep 25**
SCENESSE®	SCENESSE® EMA re-file adolescents	Q4/ 2025
	SCENESSE® in EPP Health Canada deciion marketing autoriitation	Q4/ 2025
	Distribution expansion to 120 Specialist Centers USA - CA	Q4/ 2025
Clinical, regulatory	NEURACTHEL® (ACTL) maufacturing update	Q4/ 2025
	Vitilgo Regulatory update	Q4/ 2025
	Vitilgo First patient first visit CUV107	Q4/ 2025 / Q1/2026
	Vitilgo CUV105 primary protocol complete	H1/2026
	Vitilgo CUV105 first results	H2/2026
	Variegate porphyrialgo (VP) Start CUV053	H1/2026
Communication, IR	NDR and conferences DE, USA, AUS	H2/2025
Corporate	Premarketing acivities PhotoCosmetics	Q3/2025 / Q4/2025
	AAD Meeting 2026 in Denver; USA	Q1/2026

Source: Company data ; PCR - 26.09.2025

The early-stage projects for **other Rx products** – PRÉNUMBRA® for use in stroke (AIS) and Parkinson's disease, and SCENESSE® for **XP – have been temporarily suspended. The clinical trial results achieved with** PRÉNUMBRA® Instant **appear to provide** a solid basis for **resuming the programme** for arterial ischaemic stroke **in the future**.

The results of the Phase II stroke study **CUV803** were announced in March 2025. Patients treated with PRÉNUMBRA® Instant tolerated the drug well and some showed functional improvement, while a majority showed radiological improvement or stability. These results are consistent with the previous CUV801 study.

Regional expansion has continued in the meantime, as it goes hand in hand with the expansion of the product portfolio. By the end **of 2025, around 120 treatment centres are to be established in North America (as of 30 June 2025: 104 centres).** This will enable EPP patients to be treated almost nationwide in the USA. In future, vitiligo patients will also be able to benefit from the expertise available there. In Latin America, initial steps have been taken in **Colombia** and **Argentina (**CN 17 January 2025) to treat local EPP patients through cross-border partnership agreements, **starting in CY 2026**. The formal **market approval by Health Canada** (**decision by CY Q4/25)** would also **enable broader access** for an estimated **280 EPP patients.**

An important task is **to make** the activities (spread across two continents) **scalable** for **more complex development programmes and new projects**. The study centres have been enabled to care for larger groups of patients and subjects (e.g. in the vitiligo studies). At the same time, administrative processes have been optimised so that the necessary infrastructure for treating vitiligo patients will be available at a later date.

Management is working on acquisitions to strengthen the company's overall activities. In our opinion**, M&A activities** will **only regain importance once the data obtained from the current vitiligo study (CUV105) has been evaluated.**

"PhotoCosmetics" as an integral part of the growth strategy

In addition to the development of medicinal products, the launch of a range of non-pharmaceutical consumer products (non-Rx; OTC), known as "**PhotoCosmetics",** is **being driven forward**. It is becoming increasingly clear that the efficacy and safety data collected with „Photo-Medices“ over a long period of time will be **the decisive basis for success** in this context.

CLINUVEL sees itself as the **world's first company** to develop and market a technology that **activates melanin production in the skin without exposure to sunlight**. This means that the body's natural tanning mechanism is replicated while **avoiding** the **health risks** associated with ultraviolet rays.

According to market researchers, this is in line with **growing consumer interest** in **scientifically based products and brands** recommended by dermatologists. In **March 2025**, **CLINUVEL was** prominently featured at the American Academy of Dermatology (AAD) meeting, the world's largest dermatology conference. This marked the launch **of a two-year programme** of global events, media partnerships and ambassador programmes that will make the brand accessible to the top tier of **luxury beauty brands**.

The three **target groups** identified by **the Communications, Branding & Marketing (CBM) team comprise an estimated 35 m people** worldwide and are addressed very **efficiently via digital marketing channels** (website, e-shop, ambassadors) and events. Since the beginning of CY 2025,

mainstream media and traditional trade press have also been made aware of the developing "PhotoCosmetics" range.

CLINUVEL's innovative skin health brand targets a very large market

According to McKinsey, **the luxury skincare market will be worth around US$260 billion by CY 2027**. The projected gross margins of 50-70% are attractive. The largest projected growth will come from luxury and prestige brands, with average annual growth rates of 11% and 7%, respectively.

Following the pilot launch of the polychromatic light-stabilising emulsions **CYACÊLLE and CYACÊLLE Radiant, the global market launch is planned for CY 2025, accompanied by a media campaign.** The emulsion was reportedly also given free of charge to EPP and XP patients as an adjunct therapy to SCENESSE®. We expect initial indications of market success towards the end of the summer. The launch of the **second product line** (CLINUVEL Preserve - Assisted DNA Repair) and the **third product line** (CLINUVEL Bronze for self-tanners) is planned **for CY 2026**.

CLINUVEL has set up an internal marketing department, **the "Communications, Branding & Marketing (CBM) Team"**, **for the launch of the PhotoCosmetics lines**. The "**digital first" approach** (ambassadors, CUVA, CUVIP, social media campaign) differs from that of the broader competition and does not use the traditional consumer care marketing mix, making it **significantly less risky and –** at 5-7% of the group-wide cost block – **more cost-efficient** than that of the cosmetics competition (25-30% of segment sales).

The market launch of **CLINUVEL Bronze** will shake up the industry when this innovative skin health brand is established with this groundbreaking technology from CLINUVEL. **The effort is worth it, as management has its sights set on an addressable market of US$6.2 billion per year.** Target groups include people who spend excessive amounts of time in environments with high UV radiation (such as the estimated **25 million** outdoor **extreme sports enthusiasts**), who have an increased risk of skin cancer or who are immunocompromised.

We therefore expect the CYACÊLLE product range to make a greater contribution to sales from CY 2027 onwards.

SCENESSE® remains the only approved EPP treatment until at least CY 2027

Erythropoietic protoporphyria (EPP) is an inherited genetic disorder that causes debilitating phototoxic reactions when patients are exposed to visible light. The **genetic defect that causes EPP cannot be treated causally**. To prevent symptoms, those affected can **currently only avoid sunlight** and not spend too much time outdoors. Exposure to light causes painful skin reactions in those affected, often referred to as "light allergy" (**approx. 5,500 EPP patients in the US and EU combined).**

SCENESSE® from CLINUVEL is the world's first and only approved therapy for the treatment of EPP and has been approved by regulatory authorities worldwide (EU 2014; USA 2019). **To date, over 18,500 doses have been administered to EPP patients worldwide (**equivalent to approximately 2,000 patients). Clinical studies and real-world experience have shown that SCENESSE® protects EPP patients from light and UV radiation, prevents phototoxic reactions and **enables** them **to live a life that would have been unthinkable before treatment.** The SCENESSE® implant is **implanted subcutaneously** up to six times a year by specially trained and manufacturer-certified physicians**.** It dissolves in the tissue and does not need to be removed.

EMA to decide on extension of SCENESSE® (EPP) approval in CY 2025

CLINUVEL has applied to the EMA for an extension of the approval so that EPP patients in the **older adolescent age** group **(15-17 years) can** also **be treated. The EMA's decision is still pending and is expected in CY 2025.**

There are approximately sixty known patients in France, Germany, Italy and the Netherlands. Many of these patients receive full reimbursement for their treatment – from programmes on a case-by-case basis – as payers recognise the high unmet need in adolescent EPP patients. CLINUVEL had initiated the CUV052 study in September 2022**. Ultimately, the EMA** did **not** issue **a positive risk-benefit assessment in Q2/24**, following which **CLINUVEL withdrew the formal marketing authorisation extension** and continues to explore options to make SCENESSE® available to all patients. Another study was conducted with **28 EPP patients (**aged 12-70) in three European EPP centres. The treatment results in adolescents and adults (each weighing >50 kg) are being compared in terms of efficacy and safety.

If the drug is ultimately approved for adolescents, it should be possible **to quickly generate additional sales above the AU$5 million threshold** with this adolescent patient group **from FY 2026 onwards**. We estimate the number of adolescent patients affected in Europe to be around 150, which **would correspond to** a **total addressable market for "adolescent EPP" of approximately AU$15 million p.a. (> €8.5 million).** The CUV052 study will also **support** the extension of **US approval** for 12- to 17-year-olds in the United States**.**

EMA recently made a positive decision regarding label harmonization for SCENESSE® (EPP)

The 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%) were successfully completed** in September 2025 (CN 23.09.25). The Committee for Risk Assessment in Pharmacovigilance (PRAC) of the EMA has approved this change in approval, allowing the treatment regimen in Europe to be harmonized with that in other countries (including the US FDA). European EPP patients **will therefore be able to receive year-round treatment** in the future. This decision provides a significant opportunity **to increase frequency of treatment in the EU**. We estimate the expected additional (proportional) revenue for FY 26 at a mid-single-digit amount and from **FY 27 at a double-digit million amount per year**.

Erythropoetischen Protoporphyrie (EPP) Markt (global/USA/EU 5/RoW):	Incidence:	1:140K/ www (ca. 10.000 individuals) ca. 10k/>2,5K/>2,5k/-
CLINUVEL	Registration: 2014 + 2017	in EU + in USA; SCENESSE® (16 mg Afa) Implantat adolescent Study Phase III CUV052
Competition (Company; **Product**):	Marketing	
Disc Medicine: **Bitopertin**	2027e	oral , once daily in EPP, XP, Phase III H1/25e
MITSUBISHI (MTPA): **Dersimelagon (MT-7117)**	2028e	oral , once daily in EPP, XP, Phase III extention
Source: Companies; PCR - 26.09.2025		

Competitive landscape in EPP – no competitive drug in sight before CY 2027

The synthetic drug candidate from **MTPA (MITSUBISHI TANABE PHARMA AMERICA) is called Dersimelagon (or MT-7117 in EPP and XLP; n > 300)**) and is administered orally once daily. It is not a peptide treatment, but the melanocortin-1 receptor (MC1R) activates **the same signalling pathway used by SCENESSE®. The Phase III extension study (**NCT05005975) was initiated in August 2021 – recruiting subjects – and **is expected to be completed** by **the end of 2027 (previously: mid-2025),** followed by analysis. **The second Phase III study (**NCT06144840, **n =165**), which relates to a single dose and is not yet recruiting, is scheduled to be completed in **June 2026**, according to clinicaltrials.gov. Based on the data available to date, we do not expect any efficacy advantage (high **dropout rate).**

We expect **very strict** requirements and conditions for **Dersimelagon in terms of pharmacovigilance,** as the risk of off-label abuse is significantly higher with oral treatment than with the subcutaneous implant for SCENESSE®.

On January 21, 2025, **Disc Medicine reached an agreement with the US FDA** during a Type C meeting regarding the study design for the APOLLO study. **This meeting finalized the design of the post-marketing confirmatory study for Bitopertin (Disc-1459) in erythropoietic protoporphyria (EPP),** with key endpoints established and the path cleared for the study start by mid-2025. **The completion of the Phase III study** (n =160; full enrollment after about 12 months) is **planned for November 2026**. We continue to believe that this treatment may only **reach market readiness in 2027 at the earliest**. As a co-primary endpoint, the average monthly time spent in sunlight during the last month of a six-month treatment period will be used in their confirmatory study, which is set to start in May 2025. **Bitopertin (NCT06910358) is an orally administered GlyT1 inhibitor** developed to modulate the biosynthesis of heme, a component of hemoglobin, and has been shown in studies to reduce PPIX levels in red blood cells.

Regional expansion – for EPP and vitiligo patients

The focus of regional expansion is on the US and Canada. Certified dermatologists and other specialists with particular experience with the target groups have been selected for this purpose. As the combination of SCENESSE® and phototherapy is highly effective according to the available data, it makes sense to select only those centres that already offer UVA and UVB phototherapy. **By mid-2025, a large number of US university and medical centres had already been** trained and approved for treatment with SCENESSE® (afamelanotide). **The goal is to establish an initial network of 120 centres (**as of 30 June 2025: 104, including 4 in Canada) **in 48 US states and Canada by the end of 2025** and to complete this network in the following years, thereby gaining a dominant position over the competition. The **billing codes** have been assigned and **over 100 insurers** are already connected to the programme.

A decision on the **market approval of SCENESSE® (afamelanotide) for EPP in Canada** (approx. 39 million inhabitants) **is expected in the fourth quarter of 2025**. Since 2023, Canadian patients have been receiving SCENESSE® treatment under a Special Access Programme (SAP), with insurance coverage supporting access to treatment. Formal **market approval by Health Canada** is expected to enable **broader access** to treatment in Canada, where an estimated **280 EPP patients** live.

The network of treatment centres being established in North America would not only **reach** many of the **estimated 1,300 EPP patients in the United States** (population approx. 333 million)**, but** would **also** be able to admit and treat **around 6,000 vitiligo patients per year**. While EPP requires **continuous annual treatment with up to six SCENESSE® implants**, vitiligo appears to be treatable with 85% to 95% repigmentation using a single initial treatment cycle of seven to nine doses in combination with narrowband UVB irradiation. According to CLINUVEL, **two implants may** be required for annual **maintenance therapy**.

The company is continuously exploring regional expansion opportunities to reach and treat patients outside its current reach.

In 2024, **Latin American countries** (out of a population of around 400 million, approximately 2,000 people are affected, or 1 in 200,000) introduced legislation supporting the use of medicines for patients with serious diseases. CLINUVEL has therefore entered into a **strategic partnership with Valentech Pharma**, a specialist in rare diseases. This will make the treatment option with SCENESSE® (afamelanotide) **available to around 2,000 EPP patients** on the continent through both **special access programmes** and regulatory approvals. CLINUVEL has also signed a cooperation agreement in **Colombia (**approx. 47 million inhabitants) and a distribution agreement with Diligens Salud SA in **Argentina (**approx. 46 million inhabitants). **We expect initial sales from CY 2026 on.**

The big opportunity – REPIGMENTATION – SCENESSE® in VITILIGO

In the EU, the selective JAK1/JAK2 inhibitor Opzelura® (ruxolitinib cream) from Incyte Inc. (INCY/NASDAQ-GS) **has been approved since April 2023 as the first and only topical therapy** for the treatment of non-segmental vitiligo (NSV) in adults and adolescents and children.

However, **the side effects typical** of **JAK inhibitors** limit the range of applications. **The JAK inhibitor Opzelura carries a corresponding black box warning.**

In the US, the JAK inhibitor Opzelura® (ruxolitinib) has been approved by the FDA **since July 2022** for the **treatment of vitiligo in patients with <=10% of the body surface area (BSA) affected** and is also showing promising efficacy there. Opzelura® is a topical cream that is applied twice daily as monotherapy (Q2/25: sales of US$164 m.; +35% YoY).

As a follow-up product, **Povorcitinib** (oral JAK1 inhibitor) is being tested by Incyte Inc. in Phase III trials (STOP-V1, STOP-V2; NCT06113445; NCT06113471) for the treatment of vitiligo (+ hidradenitis suppurativa + prurigo nodularis). **Recruitment has not yet begun**, with Phase III data on the treatment of vitiligo patients expected to be available in the course of CY 2026, and possible approval could then follow approximately 12 months later.

Abbvie (ABBV/NYSE) is currently testing Rinvoq® (upadacitinib) in **Phase III trials**. The oral JAK inhibitor is approved for a range of immune diseases such as RA, PsA, UC and DC. Adverse side effects also lead to a "black box warning" in this case. These warnings are also likely to become relevant for the vitiligo indication. According to the January 2025 investor presentation, **approval for the treatment of vitiligo is planned for CY 2026 (**Phase III data is expected to be published in CY 2025).

Pfizer (PFE/NYSE) has been testing the JAK3 inhibitor Litfulo® (ritlecitinib) / parent study: B7981040) in a follow-up study (NCT 06163326) in **Phase III** (N= 400) since January 2024. The primary **endpoint of the study** is planned **for Q2/27**.

Vitiligo Market (global/USA/EU 5/RoW):	Incidence:	0,5- 2 % www (>40 - 160 Mio. individuals) <160 Mio./70K/40k/-
CLINUVEL	Registration: 2028e	Phase III:CUV105; CUV107 (SCENESSE®;16 mg Afa) dark Skintype (Fitzpatrick-Skintype III-VI) Phase III: CUV107 FPI Q4/25/Q1/26
Competition (Company; **Product**): Incyte Inc: **Opzelura** (Ruxolitinib) Incyte Inc: **NCT06113445** (Povorcitinib) Abbvie: **Rinvoq** (Upadacitinib) Pfizer: **Litfulo** (Ritlecitinib) *Source: Companies; PCR - 26.09.2025*	Marketing 2022/23 2027e 2026e 2028e	 **Opzelura** (oral JAK-Inhibitor) Povorcitinib (oral JAK1-Inhibitor) Phase III (oral JAK-Inhibitor) Phase III (oral JAK3-Inhibitor)

Phase III study CUV107 – final vitiligo registration study to start at the turn of the year 2025/26

Recruitment for the **Phase III vitiligo study CUV105 (n=210; up to 7 implants + NB-UVB irradiation) was completed in May 2025, ahead of schedule,** following optimisation measures**.** The inclusion

criteria for the CUV105 study had been relaxed so that patients with vitiligo lesions (depigmentation) on the face, including the scalp and neck, could also be included. **The primary (**T-VASI 50%) **and secondary (**F-VASI; ViTiQoL, maintenance of pigmentation, safety) **endpoints,** including those assessing depigmentation of the entire body and face, **remained unchanged.** Meanwhile discussions on pricing and reimbursement have begun.

Importantly, the primary inclusion criterion for **the CUV study** remains that it **includes more severely affected patients (≥10% of body surface area (BSA)**), whereas JAKs are only eligible for patients with ≤10% BSA. SCENESSE® would be the only systemic therapy for vitiligo that **does NOT modulate** the **immune system,** as JAK inhibitors suppress the human immune response.

CLINUVEL plans to conduct at least two potentially pivotal studies before submitting the regulatory dossier. The **Phase III study CUV107** +NB-UVB; **n=200) is currently being coordinated with the authorities and** is expected to start at the turn of 2025/26. Therefore, we **do not** expect the earliest potential **market launch before CY 2028.**

If the safety and efficacy data (from approximately 1,000 treatments) from the studies are deemed sufficient by the FDA, CLINUVEL could submit a (faster) **supplemental new drug application (sNDA) for SCENESSE® for the treatment of vitiligo.** This supplemental application is required to add a new indication to the label of a drug already approved in the US (SCENESSE® for EPP). The results of the **Phase II monotherapy study CUV104** were announced in June. In light of these results, no further studies of afamelanotide as monotherapy for vitiligo patients are planned.

However, the large addressable (see below) vitiligo market argues in favour of multiple treatment options that can treat many thousands of patients. Unlike Opzelura®, we expect that **the approval of SCENESSE® for vitiligo** will be limited **to patients with darker skin tones (Fitzpatrick skin type III-VI)** and a larger area of the body affected by vitiligo, **which corresponds to approximately 60-65k addressable US patients.** Patients at high risk of infection or patients who do not respond to JAKs could benefit particularly well from SCENESSE®.

Based on experience and research findings, CLINUVEL management estimates that a US centre **can typically treat 50 new vitiligo patients per year.** Most patients will need to visit the clinic twice a week for up to 18 months to achieve a certain degree of (re)pigmentation. **Approximately 8-9 doses may be required** for approximately 90% repigmentation in a multi-year treatment cycle. However, given the burden of participating in such a clinical programme, the dropout rate for vitiligo is potentialy quite high.

In summary, CLINUVEL's management expects to be able to treat approximately 6,000 vitiligo patients in **120 US centres** in the first few years. Management estimates sales in the first two years of sales from the treatment of approximately 6,000 patients at **"US$490 to 570 m." (approximately AU$735 to 855 million).**

At a potential annual price of >AU$130k, treating 6k patients with SCENESSE® (planned first phase of expansion of CLINUVEL treatment centres in the US; approx. 9% of the addressable market) would generate **additional revenue of more than AU$735 m.**, with the potential for even higher uptake.

PHOTOPROTECTION SCENESSE® in VP - CUV040 Phase II data of interest

Variegate porphyria (VP) is **a rare hereditary porphyria disorder**. Porphyrins (cause: deficiency of the enzyme PPOX) accumulate in the liver and can attack the nervous system and skin, **leading** to the **very diverse symptoms of porphyria attacks**, typically in adulthood. Those affected develop cutaneous (skin) or neurological abnormalities, or both. **The skin symptoms are usually chronic, while the neurological symptoms typically occur in acute episodes lasting days or weeks.** Blistering on the hands and face and sensitivity to sunlight are the most common skin symptoms.

Since 2019/2020, there has been a single FDA- and EMA-approved therapy called Givlaari (Givosiran ALN-AS1) for the treatment of acute hepatic porphyria, including variegate porphyria (VP), which, however, only works on the acute symptoms; **therefore, SCENESSE® is the only effective treatment for variegate porphyria (VP).**

Givlaari is marketed by Alnylam (NASDAQ: ALNY) with an annual list price of approximately $575,000 in the US, EU and other countries. **Annual sales increased by** +29% year-on-year to US$256 million **in CY24**.

Variegate Porphyrie (VP) Markt (global/USA/EU 5/RoW):	Incidence:	1:100K/ www (<80.000 individuals) <80k/>5K/>5k/-
CLINUVEL OD-Designation (EMA)	Registration: 2028e	Phase III: CUV053 Start in H1/26
Competition (Company; **Product**): Alnylam: **Givlaari** - *Source: Companies; PCR - 26.09.2025*	Marketing 2020	akute hepatitic porphyrie und VP-patients

So only CLINUVEL (**CUV040**; Proof of Concept**, Phase IIa, Open Label Study** to Evaluate the Safety and Efficacy of Afamelanotide (16mg) in Patients with Variegate Porphyria (VP)-Related Skin Disease) has a drug candidate for VP in clinical development. All six patients reportedly **showed positive developments** – clinical symptoms were reduced and quality of life improved. **Initial data analyses** on systemic photoprotection and on dermatological symptoms **are still pending.** The first efficacy data will be crucial in determining whether SCENESSE® improves neurological (abdominal) symptoms and/or skin symptoms associated with VP.

Further efficacy studies are in the planning stage. **CUV053 is scheduled to start in CY H1/ 2026**. **We estimate that it will take approximately 3-4 years** before SCENESSE® **could be approved** (**as a Type II extension**, with 10 years of exclusivity) as the second available treatment for VP patients.

NEURACTHEL® – a generic ACTH for rheumatic and autoimmune diseases

If the **ACTH generic developed by CLINUVEL** passes the review – approximately 24 months after the ANDA submission to the FDA in the coming quarters – towards the end of 2026, approval of the NEURACTHEL® generic **(US filing CY 2026e**) for the **first indications (**paediatric spasms in children, adults with relapsing-remitting multiple sclerosis, other CNS indications) **could be granted** in the further course of **CY 2027.** We expect that a sales threshold of **US$ 30 m. on an annual basis** should then **be reached quickly**.

A modified and an instant formulation are to be tested. We definitely see the economic potential – **the ACTH market (**approved by the FDA for 24 indications**) is estimated at US$ 933 m. p.a. (>+39% YoY) for CY 2025.**

NEURACTHEL® Instant is being developed by CLINUVEL as a **generic** product**,** which means that only analytical (PK tests in humans) and statistical comparability with existing ACTH products from the original manufacturers needs to be demonstrated for approval, which **means** less time, less money and **less risk**.

As a therapy, ACTH is an alternative to corticosteroids (prednisone, etc.) that combat rheumatic and autoimmune diseases. Like corticosteroids, ACTH does not slow the progression of the disease. ACTH was first approved as a therapeutic agent in **the 1950s**. ACTH analogues are available as liquid and gel formulations (for injection) for use in severe chronic and acute neurological, endocrinological and degenerative diseases.

H.P. Acthar Gel (injection and also as a self-inject, FDA approval March 2024) was originally approved in 1952. **Acthar Gel is the main revenue driver** for Mallinckrodt Pharmaceutical plc (NYSE: MNK). **H.P. Acthar Gel has long been used off-label for** the treatment of **childhood seizures**.

ANI Pharmaceuticals (NASDAQ: ANIP) received **FDA approval for Cortrophin Gel in November 2021**. ANIP plans to expand into a range of other applications (**pre-filled syringe in April 2025) and** indications (like H.P. Acthar**,** the drug is **approved for chronic (22) autoimmune diseases,** including MS, rheumatoid arthritis (RA) and nephrotic syndrome (NS). Sales of **Cortrophin Gel are expected** to exceed **US$ 322 m. (+63% YoY) in fiscal year 2025**, **four years after market launch**, compared to ANI's projected total FY 2025 sales of > US$ 933 m.

NEURACTHEL® ACTH-Generic	Incidence:	-	
Markt (global/USA/EU 5/RoW):		>US$ 1.000 m/-	
CLINUVEL	Registration: 2027e		US-Filing CY26e; ACTH generic, liquid NEURACTHEL® Instant in MS
Competition (Company; **Product**):	Marketing		
Mallinckrodt: **H.P. Acthar Gel**		2014	chronical autoimmune desease (MS,RA,NS, etc.)
ANI Pharmaceuticals: **Cortrophin Gel**		2022	chronical autoimmune desease (MS,RA,NS, etc.)
Source: Companies; PCR - 26.09.2025			

Clinuvel targets untapped niche - competitors dominate many ACTH applications

CLINUVEL has announced that it will initially **focus** on the treatment of patients with **infantile spasms**, certain other types of **severe epilepsy in children**, and **multiple sclerosis**. We have **not** yet included the NEURACTHEL® project **in our models**.

Since January 2023, the production of NEURACTHEL® has been continuously increased on a commercial scale in accordance with cGMP standards (both active ingredient and finished product) **in collaboration with our partner.** In addition to quality, **manufacturing costs** are a key aspect of the optimisation work for generic drug manufacturers. Two different dosage forms (immediate release and modified release) are to be offered. The aim is to prepare a Drug Master File for submission to the US FDA.

The NEURACTHEL® project is **not** (yet) **included in our forecast models** due to limited details and unclear positioning and marketing.

FINANCES

FY 2024/2025 (FY 2025 for short) – Expansion and discipline

The steady financial growth reflects the company's disciplined strategy based on continuous year-on-year improvement, supported by the ongoing progress of the clinical portfolio, which provides a solid financial foundation to secure, expand and diversify future revenue streams. The continued operational expansion (**workforce, infrastructure and capacity)** over the last 12 months **is consistent** with the **five-year strategy** outlined in 2021**.**

The company reports in accordance with **Australian accounting standards**. The company's **total revenue** (**TR),** including interest and other income – the **most important topline KPI** – amounted **to AU$105.3 m.** in FY **2025,** representing an increase of AU$10.0 m. or 10.5% compared to the previous year and marking the ninth consecutive year of growth. Since the launch of the leading SCENESSE® programme **in 2016**, over **18,500 SCENESSE® implants have been administered** worldwide**,** both clinically and commercially**. Commercial sales and Special Access Scheme reimbursements increased by 7.9% to AU$95.0 m.**

In line with our expectations, total expenditure in FY 2025 increased by AU$ 9.1 m. (+20% YoY) to AU$ 53.7 m, reflecting planned investments. The company is **in the midst of a second phase,** which aims to increase the number of trained and approved specialist centres in North America to 120 centres in 48 US states and Canada by the end of 2025, with a focus on "experienced sites". The **network of centres will make** treatment **accessible** to **vitiligo patients** in due course**,** while clinical trials are ongoing and regulatory applications are being submitted.

The **item Other income** in FY 2025 includes a **robust cash reserve position**, with cash and cash equivalents, including term deposits**,** increasing by AU$ 40.1 m. (+29% YoY) to **AU$ 224 m. This gives room for M&A activities.**

The company benefited from high interest income from Australian dollar and US dollar-denominated term deposits, which generated **AU$ 9.4 m.** in revenue, an increase of AU$ 2.1 m. (+30% YoY) compared to FY 2024. In **light of forecasts of possible interest rate cuts** in Australia and the US, management recently extended the terms of term deposits to a weighted average of 309 days (previous year: 276 days) with a weighted average yield of 4.70% (previous year: 5.22%).

Total expenses increased by AU$ 9.1 m. (+20% YoY) **to AU$ 53.7 m. in fiscal year 2024** to directly support the planned expansion of activities within the Group. As in the past, expenses continued to be strictly controlled and measured precisely against the achievement of objectives.

Personnel costs increased by AU$5.9 m. or 31% YoY (previous year: +39% YoY), primarily due to an **increase in the number of employees**, particularly in operations, clinical development and **c**ommunications, **b**randing and **m**arketing („CBM"), but also in management functions. The majority of staff are employed outside Australia, so a portion of the increase was influenced **by the weaker Australian dollar**.

Non-cash **share-based compensation** expenses **decreased** by AU$ 4.1 m. (-67% YoY) to AU$ 2.0 m.

The Group's **administrative expenses** remained at AU$ 4.5 m. The efficiency measures implemented had thus paid off.

Material and ancillary costs in FY 2025 rose to AU$ 4.5 m. (+9% YoY) as development work intensified, particularly at **the R&D centre in Singapore**. The Singapore centre **had been expanded in size and capacity** to support ongoing work on NEURACTHEL®, PRÉNUMBRA® and the PhotoCosmetics range. Logistics expenses increased by 10% YoY to just under AU$ 4 m.

Communication, branding and marketing (CBM) expenses totalled **AU$ 4.4 m., an increase of 100% compared to FY 2024**, as management systematically builds the foundations for market presence and seeks greater visibility among a broader global audience. A significantly higher number of marketing events were booked in FY 2025.

Clinical and non-clinical development expenditure totalled **AU$7.4 m., representing an increase of 215% compared to FY 2024**, reflecting the strategic focus on advancing various clinical programmes (in particular the Phase III CUV105 study for the treatment of vitiligo, which was fully recruited in May 2025; but also the Phase II pilot monotherapy study CUV104) to create future revenue streams. **Clinical trial costs** are expected **to fluctuate accordingly** as patients progress through the various trial phases. The leading programmes in vitiligo, VP continue to advance. At the same time, preclinical work on melanocortins such as NEURACTHEL® is being pursued to diversify risks and prepare multiple future revenue streams.

For FY 2025, the company reported a **net profit before tax of AU$ 51.6 m.** on 28 August 2025**, representing an increase of AU$ 0.9 m: or 2% YoY**. This growth is based primarily on successful financial management and the achievement of strategic growth targets, coupled with strict expenditure discipline. Net profit after tax of AU$36.2 m. represents an increase of AU$0.5 m. or 1.5% YoY. The company achieved a decrease in current taxes payable of AU$ 1.13 m. (-7% YoY), resulting in the average **tax rate falling by around 3 percentage points to 28% in the current year**, as in the previous year**. Earnings per share (basic) increased from 71.5 cents per share to 72.2 cents per share**.

Maintaining a solid balance sheet remains a strategic priority for CLINUVEL. This is reflected in an increase in total assets of AU$ 37.8 m. and an **expansion of total liabilities of AU$ 2.8 m., resulting** in a further improvement in net asset position of +19% YoY to AU$ 240.8 m. and an **improvement in gearing**.

Operating cash flow of AU$ 41.1 m. (previous year: **AU$ 37.1 m.)** was primarily generated by global revenues from SCENESSE® sales, which **totalled AU$ 93.8 m. (+12% YoY).** Interest income from cash deposits remained at AU$ 7.5 m.

We expect initial results from the ongoing CUV105 vitiligo study in CY H2/26. News on the future manufacture of the generic drug NEURACTHEL® (ACTH) could be available by CY Q4/25. **The potential expansion of SCENESSE® (initially in CY 2025e label harmonisation + adolescent patients in the EU, then CY 2028e for vitiligo) is complemented by the growing OTC portfolio.** Added to this would be the first US sales of NEURACTHEL® (ACTH) in 2027e, which we are not currently factoring into our model.

PCR estimates for FY 2026 - FY 2028 - Revenue and OPEX modelling

The company has not published any guidance. A three-year budget plan is expected to be published in the second half of 2025.

According to our estimates, revenue (including interest income) will initially grow **first by 20%, then by 17%, and finally by 26% in FY 2028,** once regional expansion (EPP in the US) and indication extensions for SENESSE® (in EPP for adolescents; label adjustment EU-US; in vitiligo) are achieved and fully implemented.

26.09.2025	CLINUVEL sales (AU$ m)						
	2023	2024	2025	2026e	2027e	2028e	2025e-2028e period
Indication total	**78,0**	**88,2**	**95,0**	**113,8**	**132,7**	**167,2**	**596,8**
SCENESSE® in EPP - adults patients	**78,0**	**88,2**	**95,0**	**110,7**	**126,1**	**140,4**	**560,4**
SCENESSE® in EPP - adolescent patients	**0,0**	**0,0**	**0,0**	**3,0**	**6,0**	**10,5**	**19,5**
SCENESSE® in XP	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
SCENESSE® in VP	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,5**	**0,5**
Vitiligo	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**12,0**	**12,0**
-							
NEURACTHEL® ACTH-generic - MS etc.	**0,0**	**0,0**	**0,0**	**0,0**	**0,2**	**1,8**	**2,0**
PRÉNUMBRA® - Stroke (AIS)	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
-							
PhotoCosmetics	**0,0**	**0,0**	**0,0**	**0,1**	**0,4**	**2,0**	**2,4**
Indication	**Risk adjusted Sales (AU$ m)**						
total	**78,0**	**95,3**	**92,5**	**99,6**	**104,6**	**118,6**	**509,4**
SCENESSE® in EPP - adults patients	**78,0**	**95,3**	**92,5**	**97,0**	**99,4**	**99,6**	**483,8**
SCENESSE® in EPP - adolescent patients	**0,0**	**0,0**	**0,0**	**2,6**	**4,7**	**7,5**	**14,8**
SCENESSE® in XP	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
SCENESSE® in VP	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,3**	**0,3**
Vitiligo	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**8,2**	**8,2**
-							
NEURACTHEL® ACTH-generic - MS etc. **	**0,0**	**0,0**	**0,0**	**0,0**	**0,1**	**1,1**	
PRÉNUMBRA® - Stroke (AIS)	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**	**0,0**
-							
PhotoCosmetics	**0,0**	**0,0**	**0,0**	**0,0**	**0,3**	**1,9**	**2,3**
26.09.2025	**Probability of authorisation * (Tufts DiMasi)**						
Phase 1	13%						
Phase 2	21%						
Phase 3	61%						

* = Probability of a clinical clinical candidate to be admitted

** = not considered in forecast model

Source: PCR

CLINUVEL's sources of income (risk-adjusted) will become increasingly diversified in the future. We use the scientifically determined adaptation pattern from Tufts University, USA (Tufts-DiMasi data) as a guideline for the probability of approval.

In our opinion, the personnel cost ratio will decline slightly in FY 2026e ff, while we **expect** the **R&D ratio to increase** in FY 2026e and FY 2027e, as we anticipate that several **important Phase III clinical** vitiligo **programmes**, **CUV105 and CUV107, and the start of the VP study CUV053** will be conducted during this period. In our opinion, the highly efficient implementation of the clinical trial programmes in-house (compared to complete outsourcing to CRO service providers) will keep the cost increase manageable in absolute terms.

The **manufacturing supply chain** is to be better integrated, which could be achieved through further development of internal capabilities or strategic acquisitions.

Marketing activities will be complemented by digital campaigns featuring CLINUVEL ambassadors, targeted advertising on social media and articles in high-profile media outlets. With the market launch of the three OTC products in the "PROTECT" sun protection and care range – pre-marketing is now scheduled **to start at the end of CY 2025** – we expect an **above-average increase** in the **C**ommunication, **B**randing and **M**arketing (**CBM)** income statement item at the beginning of the period.

The income tax rate remains stable at 30% of EBT in our modelling in the detailed planning phase. The **EPS** KPI **will increase between FY 2026 and FY 2027 in line with net profit**, as we **do not** expect **any significant capital increases**.

DCF model

Our DCF analysis takes organic development (excluding acquisitions) into account. We expect growth to accelerate in FY 2026 and FY 2027 (compared to the period before (see above).

After the detailed planning phase (until FY 2028), the expected growth in the DCF calculation falls to **11% p.a. onwards, which is probably a conservative assumption given the company's plans.** We have calculated the terminal value using a perpetual growth rate of 1%, which is also conservative. The tax rate used in the DCF is approximately 32%, which is based on the company's history (+ risk premium). This results in a rounded **weighted average cost of capital (WACC) of approximately 8.5%** as the basis for the discount factor.

Using the method described above, the DCF valuation results in an enterprise value of **AU$ 31.39.**

CLINUVEL Pharmaceutical Ltd. - DCF Model											
26.09.2025		Phase I detailed earnings-forcast			Phase II growth forcast						stabile Phase - III
Capitalized earnings	30.06.2025	2026e	2027e	2028e	2029e	2030e	2031e	2032e	2033e		2034e
CAGR in Phase II											11,0%
E A T	**36,17**	**48,23**	**61,01**	**75,98**	**84,34**	**93,62**	**103,91**	**115,34**	**128,03**		**142,12**
Discounting period in years	-0,24	0,76	1,76	2,76	3,76	4,76	5,76	6,76	7,76		**7,77**
growth-adj. current yield:	4,38%	4,38%	4,38%	4,38%	4,38%	4,38%	4,38%	4,38%	4,38%		**4,38%**
Company-specific risk premium	4,09%	4,09%	4,09%	4,09%	4,09%	4,09%	4,09%	4,09%	4,09%		**4,09%**
EAT growth in the stable phase III											**1,00%**
Discount rate		8,46%	8,46%	8,46%	8,46%	8,46%	8,46%	8,46%	8,46%		7,46%
Present value		**0,94**	**0,87**	**0,80**	**0,74**	**0,68**	**0,63**	**0,58**	**0,53**		**7,66**
Present value (AU$ m)	**36,17**	**45,35**	**52,89**	**60,73**	**62,15**	**63,61**	**65,10**	**66,62**	**68,18**	Phase III:	**1.088,93**
Enterprise value (AU$ m)		Phase I:	**134,41**					Phase II:	**386,38**	Total:	**1.573,54**
Current market value (AU$ m)											**566,44**
The enterprise value corresponds to a value per share in AU$ of											**31,39**
compared with the current share price in AU$ of											11,30
this corresponds to a price potential of											177,80%
Blended Valuation (75% : 25%; DCF : EV/EBIT)											26.09.2025
DCF	**31,39**	**AU$**						**75%**	**23,54**	**AU$**	**26,06**
EV/EBIT (FY26e)	**10,08**	**AU$**						**25%**	**2,52**		

Quelle: Company information; PCR

Nasdaq uplisting at just the right time – from Level I to Level II by the end of 2025

In addition to regulatory changes in Europe, we see the uplisting on Nasdaq as the **next growth catalyst**, which **is coming at just the right time**. The recently started **interest rate cut cycle of the FED** is likely to be very helpful in this context, as falling interest rates are associated with rising stock prices, particularly for biotech companies.
The **uplisting will significantly improve CLINUVEL's visibility** in the United States, market access and **engagement with key institutional investors**. The initiative reflects the growing importance of CLINUVEL's American **shareholder base.** While less than 20% of shares were held by institutional investors in 2019, the FY 2025 annual report now shows that around 34% of shares are held by institutional investors. CUV has around 65% foreign investors, with around 35% coming from Australia.

Since its introduction in 1993, **Nasdaq Biotechnology™ Index (NBI)** has been the leading market barometer and represents by far the world's **largest capital market for biotechs**.
Many ETFs, especially those with strong capital, refer to the **highly liquid NBI index**.

The foreseeable **growing importance of the North American markets** will certainly attract investor interest in this unique business model, supported by the efforts of CLINUVEL's investor relations team. Investors there pay particular attention to the longer-term aspects of business models that are appropriate to the specifics of pharmaceutical development. Biotech stocks are among the investments with the highest investment risks, which is particularly true for young start-ups that typically have capital requirements for several years but do not yet have a marketable product.

CLINUVEL, on the other hand, has been profitable for over nine years, has no debt, but rather AU$224 m. in free cash flow, and is poised for a growth spurt. In short, it is a business model with a sought-after opportunity/risk profile, as the history of the index heavyweights clearly shows. Heavyweights include well-known names such as **Amgen, Gilead Sciences, Regeneron Pharma**, and **Vertex Pharmaceutical**. All of them are prominent drug developers that draw a great deal of investor **attention to the biotech sector**. The total market capitalisation of the **Nasdaq Biotechnology™ Index (NBI)**, with its more than 250 stocks, now stands at around **US$1,220 billion**.

The **significance of peer evaluation in the CLINUVEL case** therefore takes a back seat to the DCF analysis, which we will also take into account in our approach.
On 22 August 2025, the company announced its intention to upgrade its American Depositary Receipt (ADR) programme in the US **from Level I to Level II on the Nasdaq**. This is expected to take place by the end of 2025, subject to successful review by the Securities and Exchange Commission and the fulfilment of additional listing requirements.
No capital increase is proposed as part of this measure.

Management emphasises that **CLINUVEL's** primary **ASX listing will remain** unchanged**.** Its home exchange is the Australian Securities Exchange (ASX), where Clinuvel's shares are listed on **the S&P/ASX 300**, whose market **capitalization is significantly lower**. The heaviest weighting is plasma and vaccine manufacturer **CSL Limited,** with a market capitalisation of over AU$96 billion**.** In our opinion, 39 biotech companies (rank 5: CLINUVEL) play a rather minor role in the index.

Summary of valuation

We derive our price target as **a** (**75:25) average from the valuation multiple (EV/EBIT)** of the peer groups (25%) on the one hand and the PCR-DCF analysis (75%) on the other. Based on the blended valuation, the value of the company is **AU$26.06 per share** (previously: AU$19.27 per share).

In doing so, we take into account the company and investment risk where applicable. The risk/reward ratio has recently improved, which is why we are raising the target price to **AU$ 26.50**

FINANCIAL KEY FIGURES

P&L (in AU$m)	2023	2024	2025e	2026e	2027e	2028e
Total Revenues	**78,321**	**88,178**	**95,018**	**113,750**	**132,655**	**167,150**
Total interest income	3,906	7,325	9,431	11,174	12,851	3,906
Total other income (loss)	0,763	-0,197	0,852	1,084	1,327	1,756
Total revenues, interest and other income	**82,990**	**95,306**	**105,300**	**126,007**	**146,833**	**172,812**
Expenses						
Personnel-related	-13,577	-18,918	-24,853	-25,289	-25,364	-27,165
Share-based Payments	-8,990	-6,107	-2,001	-4,792	-5,309	-4,683
Materials and related expenses	-12,063	-5,201	-2,674	-3,842	-4,928	-4,968
Clinical and non-clinical dev.	-1,268	-2,348	-7,404	-8,420	-7,365	-6,496
Finance, corporate, general, legal, insurance, IP	-4,516	-6,197	-5,470	-4,679	-5,456	-6,875
Commercial distr.; Communication branding and marketing	-3,895	-5,819	-8,358	-10,398	-12,106	-14,712
Depreciation and amortisation	-0,789	-1,142	-1,181	-1,273	-1,484	-1,870
Changes in inventories	7,688	1,107	-1,805	1,729	2,218	2,236
Total expenses	**-37,412**	**-44,627**	**-53,747**	**-56,964**	**-59,794**	**-64,533**
Profit before income tax	45,579	50,679	51,553	69,044	87,039	108,278
Income tax expense	**-14,974**	**-15,043**	**-15,380**	**-20,599**	**-25,967**	**-32,304**
Operation profit after income tax	30,605	35,636	36,173	48,445	61,072	75,975
Net profit for the year	**30,605**	**35,636**	**36,173**	**48,445**	**61,072**	**75,975**
Exchange differences foreign exchange translation of foreign operations	-1,454	0,139	-2,379	0,000	0,000	0,000
Total comprehensive income for the period	**29,150**	**35,775**	**33,793**	**48,445**	**61,072**	**75,975**
Number of shares (millions)	49,830	50,130	50,130	50,130	50,130	50,130
Diluted number of shares (millions)	49,830	50,130	50,130	50,130	50,130	50,130
Basic earnings per share - cents per share	**58**	**71**	**67**	**97**	**122**	**152**
Diluted earnings per share - cents per share	**58**	**71**	**67**	**97**	**122**	**152**
Dividend per share - cents per share	**5**	**5**	**5**	**7**	**9**	**11**

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

Cash flow statement (in million AU$s)	2023	2024	2025e	2026e	2027e	2028e
Cash flow from operating activities	36,91	37,05	41,10	44,53	57,32	68,28
Cash flow from investing activities	-1,028	-5,576	-0,299	-0,296	-0,345	-0,434
Cash flow from financing activities	-2,240	-3,572	-2,939	-2,507	-3,633	-4,275
Change in cash and cash equivalents	**33,644**	**27,906**	**37,859**	**41,723**	**53,338**	**63,573**
Cash and cash equiv. end of the period	156,814	183,868	224,106	265,829	319,167	382,740

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

Balance sheet (in million AU$s)	2023	2024	2025e	2026e	2027e	2028e
Fixed assets	***3,036***	***7,905***	***7,312***	***6,335***	***5,196***	***3,760***
Intangible assets	1,018	0,923	0,591	0,591	0,591	0,591
Property, plant and equipment	2,018	6,982	6,721	5,744	4,605	3,169
Financial assets	0,000	0,000	0,000	0,000	0,000	0,000
Current assets	***188,548***	***220,733***	***260,389***	***309,265***	***369,821***	***446,567***
Inventories	9,519	10,627	8,821	10,560	12,316	15,518
Trade receivables	22,215	26,238	27,461	32,875	38,339	48,309
Other receivables	0,000	0,000	0,000	0,000	0,000	0,000
Cash and securities	156,814	183,868	224,106	265,829	319,167	382,740
Other assets	2,130	2,485	4,049	4,049	4,049	4,049
Total assets	**193,714**	**231,124**	**271,750**	**319,649**	**379,066**	**454,376**
Shareholders' equity	***164,631***	***203,011***	***240,809***	***286,747***	***344,186***	***415,885***
Reserves	164,631	203,011	240,809	286,747	344,186	415,885
Minority interests	0,000	0,000	0,000	0,000	0,000	0,000
Accrued liabilities	***1,581***	***2,046***	***2,501***	***2,501***	***2,501***	***2,501***
Accounts payable	***24,744***	***23,840***	***25,020***	***26,981***	***28,959***	***32,570***
Interest-bearing liabilities	0,000	0,000	0,000	0,000	0,000	0,000
Liabilities from trade payables	7,650	7,109	9,945	11,905	13,884	17,494
Other non-interest-bearing liabilities	17,094	16,731	15,076	15,076	15,076	15,076
Other liabilities Other liabilities	***2,758***	***2,226***	***3,420***	***3,420***	***3,420***	***3,420***
Total liabilities	**193,714**	**231,124**	**271,750**	**319,649**	**379,066**	**454,376**

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

Overview of key figures	2023	2024	2025e	2026e	2027e	2028e
Key valuation figures						
EV/Sales	10,72	7,30	4,50	3,01	2,58	2,05
EV/EBITDA	19,78	14,46	9,87	5,79	4,52	3,22
EV/EBIT	20,15	14,84	10,15	5,92	4,61	3,28
P/E RATIO	39,48	23,12	19,28	11,69	9,28	7,46
Price/book value	6,054	4,074	2,706	1,975	1,646	1,362
Profitability ratios in %						
Gross margin	95,4%	95,1%	96,2%	99,1%	99,0%	99,4%
EBITDA margin	54,2%	50,5%	45,6%	52,0%	57,0%	63,6%
EBIT margin	53,2%	49,2%	44,3%	50,9%	55,9%	62,4%
Pre-tax margin	53,2%	57,5%	54,3%	60,7%	65,6%	64,8%
Net margin	32,2%	40,6%	35,6%	42,6%	46,0%	45,5%
ROE	17,4%	19,5%	15,2%	18,4%	19,4%	20,0%
Key productivity figures						
Turnover/employee (in AU$ thousand)	824,43	899,78	826,24	861,74	878,51	1.106,95
Net revenue/employee (in AU$ thousand)	322	364	315	367	404	503
Number of employees	95	98	115	132	151	151
Key financial figures						
Equity ratio	85,0%	87,8%	88,6%	89,7%	90,8%	91,5%
Dividend yield	0,3%	0,3%	0,4%	0,6%	0,8%	0,9%
Working capital/sales (in %)	30,8%	33,7%	27,7%	27,7%	27,7%	0,0%
Depreciation/sales (in %)	1,0%	1,3%	1,2%	1,1%	1,1%	1,1%
Tax rate (in %)	32,9%	29,7%	29,8%	29,8%	29,8%	29,8%

Source: PCR

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Company	Analysts	Date	Recommendation / Target price
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	09 September 2024	Buy/AU$ 26.10
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	10 February 2025	Buy/AU$ 19.27
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	7 March 2025	Buy/AU$ 22.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	26 June 2025	Buy/AU$ 22.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	30 September 2025	Buy/AU$ 26.50

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