



BUY (Buy)

Price Potential
+86.6%

Price Target
Stock Price*

14.50 AU\$ (25.00)
7.77 AU\$

*Closing price on the ASX, Sydney
(13/10/2026)

CLINUVEL Pharmaceuticals Limited

ASX: CUV – Nasdaq - ADS: CUVL,

Frankfurt Stock Exchange: UR9 - ISIN: AU 000000CUV3 - WKN: AOJEGY



Sustainably profitable – on track to become a multi-product company –
Consistent risk reduction – Full Nasdaq listing under discussion



SHAREHOLDER STRUCTURE

Free Float	76,4%
Inst. Investors	34,0%
Dr. Ph. Wolgen (CEO)	6,8%
JPMorgan Chase	6,5%
Vanguard Group	5,2%
Ender 1, LLC	5,1%

SHARE BASIC DATA

Ticker (Bloomberg)	CUV:AU
Number of shares (in millions)	50.1
Free float (in %)	76.4%
Market capitalisation (in AU\$m)	389.4
Trading volume (Ø-100 days; in AU\$ k)	1,141
52-week high (in AU\$)	13.48
52-week low (in AU\$)	7.73

FINANCIAL CALENDAR

AGM	06.11.2026
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The key performance indicators (KPIs) for **business performance in FY26** demonstrate a **sustainably profitable business model**, which is being used to expand the product portfolio according to plan without losing sight of the associated development risks. With NEURACTHEL® Instant (ACTH) and SCENESSE® for the treatment of vitiligo, **CUV is evolving into a multi-product company**.

A disciplined spending policy is expected to ensure positive free cash flow and growing net cash in the coming quarters, even amid a temporary increase in investments. The first submission for national approvals in the EU for the generic version of **NEURACTHEL® Instant**—which will then become the second major revenue driver—is still planned for CY 2026. Work is also progressing toward the approval (~CY 29) of **SCENESSE® for the treatment of vitiligo—a major future revenue source** and thus a central pillar of the equity story.

Here (CUV107 pivotal Phase III), based on the experience from the CUV105 Phase III trial, the timeline is planned **with a larger time buffer** (vitiligo NAV declines). In the foreseeable future, the **U.S.** will become **the most important market**. We view the discussed **full listing on the Nasdaq** as potentially positive news. Additional investor groups on the world's largest biotech exchange will be targeted in the future. Specific timelines (for due diligence; executive board and AGM resolutions, approvals, etc.) have not yet been determined.

Given the high valuation of **the Nasdaq Biotechnology™ Index** from an analyst's perspective, this represents a good buying opportunity. A possible **delisting from the ASX in Sydney and discontinuation on the Frankfurt Stock Exchange** would be a logical step and is likely **to weigh on the stock temporarily**.

The regulatory path for **SCENESSE® for the treatment of vitiligo** is Europe first, with U.S. approval expected to follow. (in H2/CY26: CUV107 begins pivotal Phase III; CUV105 topline results released).

The regulatory agency will apply the "totality of evidence" approach in its evaluation of SCENESSE®. This is a relatively patient-friendly and practical approach that **reduces the risk of approval**. With the new timeline of the development-pipeline, **we are adjusting our estimate, which leads to the less favorable risk profile and lowers our target price**.

FY end 30 June; in AU\$ m	(25-29e)	2025	2026	2027e	2028e	2029e
Revenue	2.0%	95.02	94.02	85.62	87.84	103.02
EBIT	-1.5%	41.27	40.53	33.44	34.26	38.92
EBIT margin		43.4%	43.1%	39.1%	39.0%	37.8%
Net income	-1.4%	36.17	33.92	29.97	30.84	34.20
EPS in AU\$	-1.4%	0.72	0.68	0.60	0.62	0.68
Dividend per share in AU\$		0.05	0.05	0.05	0.05	0.06
EV/Sales		6.57	5.12	4.31	4.20	3.58
EV/EBIT		15.1	11.9	11.0	10.8	9.5
P/E ratio		18.0	15.1	13.0	12.6	11.4

Source: Company data, PCR

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INVESTMENT THESES

CLINUVEL (CUV) is a pioneer in "photomedicine" and is benefiting from the rapidly growing awareness of light-related health risks. CUV is one of the few biopharmaceutical companies to be consistently profitable. The company **markets its drugs independently and is highly profitable** in the U.S. 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 genetic disorder.

Strong internal financing capacity is a priority and is focused on three core projects, so that, in our assessment, there will be **no** need to tap **external sources of financing** in the foreseeable future. On the other hand, the Board of Directors intends to be more conservative in **its use of profits** (special dividends, share buybacks) during this concentrated investment phase.

CUV is an **atypical biotech company**. It has been **profitable** for the tenth consecutive year, with an EBIT margin of approximately 43% over the past two fiscal years. A **dividend was paid** in September 2026 for the ninth consecutive year. The company intends **to grow** more rapidly in the future and is developing a limited number of additional drugs and cosmetics to that end.

The existing SCENESSE® business can **generally expect revenue growth and high margins in the near future**, as we believe no alternative EPP treatments are expected before CY27, as indicated by developments among market competitors. **By contrast**, the **approval (~FY29) of SCENESSE®** for the treatment of **(non-segmental) vitiligo (NSV) is likely to trigger a quantum leap in CLINUVEL's revenue and earnings**.

Non-segmental vitiligo (NSV) **is the most common form of vitiligo** and accounts for over 90% of those affected. It is characterized by symmetrical, bilateral white patches on the skin. **Patients with less severe disease ($\leq 10\%$ of body surface area (BSA)) can be treated** with immunomodulators (so-called JAKs). **These cannot be used in severely affected individuals** (patients with $\geq 10\%$ BSA). In these cases, SCENESSE® would be a good option. However, in our opinion, patients at high risk of infection or those who do not respond to JAKs such as Opzelura® would also be suitable candidates.

SCENESSE® would thus be the only systemic therapy for vitiligo that **does NOT modulate the immune system**. Recruitment of **severely affected patients ($\geq 10\%$ of body surface area (BSA); $n > 300$)** for the **CUV107 study (SCENESSE® for the treatment of vitiligo)** is scheduled to begin in a few months and be completed in H2/27. After 5 months of treatment and 6 months of follow-up, **initial results could be expected in H2/28. Approval could thus follow in CY29.**

The decision by EU regulatory authorities regarding the proposed expansion of **SCENESSE® (EPP) use to adolescent patients in Europe**—is expected to follow submission of a revised application by the end of CY 2027—and is likely to provide an additional growth boost for CY 2028.

Investor relations efforts will be further intensified, which will significantly improve visibility in the capital markets. An increasing number of shareholders are from the U.S.; visibility and communication there will be significantly expanded, and regulatory requirements for the company are increasing. The **Nasdaq listing of the ADRs (now ADSs) to Level II was completed in July 2026**. But that's not all: a full **Nasdaq listing is currently under discussion. If implemented, it would require approval from regulatory authorities, the courts, and shareholders**. This would open the door to additional investor groups—**particularly among key institutional investors**—in the U.S.



Future pharmaceutical activities will focus on North America; therefore, management is evaluating whether a **U.S.-focused business group and a Nasdaq listing** would better align with the company's future direction.

For high-growth biotech companies—with their many cross-border activities—there is usually no way around the Nasdaq, if only because of market liquidity and the specialized investor base. A capital increase in this context is not planned. **The primary listing** on the Australian Securities Exchange (ASX), as well as the listing in Frankfurt, **could be discontinued in return**.

The updated development plans for the drug candidates result in a **lower NPV**. This **applies** in particular to **SCENESSE®** for the treatment of **vitiligo, where lessons have been learned from the CUV105 trials and more time is being allocated for the CUV107 trial plan**.

The market environment is also evolving. Vitiligo, which for a long time was dismissed by insurance companies as a cosmetic issue, is now recognized as a reimbursable condition (TAM > 4.5 billion annually). **Drugs in the JAK inhibitor class are approved for milder cases. In contrast, SCENESSE® is intended for severe cases in patients with relatively darker skin tones and could even be used when JAK inhibitors fail.** Overall, we believe this development is likely to be beneficial for CLINUVEL, as there is little overlap in the target populations and the drugs have different mechanisms of action.

Our valuation is based on a weighted average of **85:15** derived from (1) a risk-adjusted DCF (AU \$14.79, previously \$23.94 AU) and (2) EV/EBIT (27e) of AU\$12.08. The **risk-return ratio has deteriorated**. We are **adopting** a more cautious stance and **lowering** the **target price from AU\$25.00 to AU\$14.38** (in Short AU\$ 14.50).

The market is primarily focused on the **risk-reward profile of the planned approval of SCENESSE®** for the treatment of vitiligo (~FY29) as the largest potential growth driver. We currently estimate the probability of approval (**Phase III CUV107 study with initial data in H2/CY27**) at 75% (i.e., NPV in the U.S. market: ~US\$ 367 million). We currently value the SCENESSE® franchise **at an NPV of ~US\$ 655 million (=AU\$ 924 million)**. We are including the NEURACTHEL® franchise (generic ACTH—infant spasms + adult MS) for the first time **with an NPV of ~US\$ 310 million (=AU\$ 437 million; 1.00 US\$/AUS\$ = 1.41)**. Given its track record and probability of success, the **CUV stock is therefore significantly undervalued from an analytical perspective**.

In the near term, the pending EMA decisions on expanding the indication — for the **older adolescent age group (15–17 years)** — for **SCENESSE® (EPP)** could trigger growth momentum and upgrades in the capital markets.

In our view, the strategic focus and risk reduction have **fundamentally increased the stock's attractiveness**. The significant (+10–20%) increase in peer valuations points in the same direction.

The **approval (~FY 2029) of SCENESSE®** for the treatment of **vitiligo and the country-by-country approval (~FY 2027) of the generic drug NEURACTHEL® (ACTH) in a number of EU member states** are likely to be the biggest potential growth drivers. **By contrast**, the **updated timeline** for the development candidate (CUV107) **reduces its NPV**, which serves as the basis for the valuation and the target price.





The potential full Nasdaq listing, will, in our view, be well-received and should therefore be implemented promptly. The simultaneous delisting from the Australian and German stock exchanges discussed by management is likely to have only a temporary negative impact, in our view, **as the Nasdaq valuation is relatively high.**

We reaffirm our BUY recommendation for the shares of CLINUVEL Pharmaceuticals Ltd.



STRATEGY

Profitability - Diversification - Growth

The leading product is the prescription implant SCENESSE® (afamelanotide 16 mg). It is approved for commercial distribution in Europe, the U.S., Israel, Australia, and Canada 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 also provided through special access programs (e.g., Switzerland).

CLINUVEL operates an integrated business model. The group **is debt-free and has been profitable for ten years.** Notably, the company had to invest only AU\$150 million in the development of SCENESSE® for EPP—a fraction of the industry standard. **Key functions** (R&D, regulatory affairs, sales and distribution, branding) are **carried out in-house** as much as possible rather than being outsourced to third parties. **In the future, key production steps will also be organized internally,** which is only logical given the targeted approvals and the associated strong growth in product volumes. To this end, and for product development (controlled-release formulations for liquid peptides), the RD&I unit **VALLAURIX** in Singapore is currently undergoing massive expansion.

The development pipeline **has been focused on the three advanced clinical projects** involving afamelanotide (SCENESSE®) for **vitiligo; ACTH, EPP, and VP—down** from a total of **nine projects** previously, **six of which were in clinical development.** The decision was driven by the highest prospects for success and the fastest paths to regulatory and commercial success. For this reason, the generic drug NEURACTHEL® (**autoimmune and CNS disorders**) is also being **further developed and is expected to be launched in the near future.**



Catalysts and Calendar		CY 2026 - CY 2027
Commercial growth		
SCENESSE®	SCENESSE® EMA filing adolescent use in EPP	H2/ 2027
	SCENESSE® in EPP Health Canada decision marketing authorisation	H2/ 2026
	Vitilgo CUV105: top line results	Dez 26
	Vitilgo CUV105: complete results	H1/ 2027
	Vitilgo CUV107: EMA Scientific Advice	H1/ 2026
	Vitilgo CUV107: Phase III start recruitment	Nov 26
	FDA Vitilgo Meeting	H1/ 2027
	Vitilgo CUV107: Phase III recruitment completed	H2/ 2027
ACTH-NEURACTHEL®	EU: 1st filing(s) marketing autorisation	H2/ 2026
	liquid controlled-release formulation: top line precl. result	H1/2026
	preclinical complete result	H2/2026
VLRX-L	liquid controlled-release in production (CDMO)	H1/2027
Pipeline	new peptides in liquid controlled-release: precl. Data	H1/2027
Corporate, Finance, Commercial	full Nasdaq quotation	H1/2027
	CLINUVEL will move HQ into USA	H1/2027
	AAD Meeting 2027 in San Francisco; USA	H1/2027
R&D + Innovation	VALLAURIX, Singapore: complete construction of expansion R&D+I Centre	H2/2026
	New Peptides in liquid controlled release - precl. data	H1/2027
Source: Company data as of 26.08.26; PCR - 13.10.2026		

CLINUVEL Chart – Catalysts + Calendar

CLINUVEL remains in investment mode to pursue diversification. Plans include the launch of CUV107 (H2/CY26), full CUV105 results (H1/CY27), the PhotoCosmetics launch (M-lines, Preserve, and Bronze in H2/CY27), and the further **expansion of its U.S. presence and RD&I Centre in Singapore.** Revenue streams are expected to diversify increasingly through vitiligo (TAM > US\$ 4.5 billion), NEURACTHEL® (TAM ~ US\$ 1.3 billion), and other programs. The strong cash position enables self-financed implementation without dilution. The company has thus further strengthened the foundation for its **transition from a single-product to a multi-product company** and is clearly positioning itself for the **North American market as its future focus.**

In the meantime, **regional expansion** has continued in a targeted manner, as it goes hand in hand with the expansion of the product portfolio. By the end of **2027, approximately 190 treatment centers are to be established in North America (as of June 30, 2026: 134 centers).**

CLINUVEL's key research activities are currently conducted in Singapore, while commercial and clinical activities are managed from the United Kingdom, the European Union, and the United States. A key task is **to make** the processes and necessary infrastructure **scalable** for **more complex development programs and new projects, as well as for the ongoing** treatment of vitiligo patients.

The Executive Board is therefore considering changing CLINUVEL's corporate holding structure. Furthermore, the company is considering seeking a full listing of its common stock on the Nasdaq



Stock Market ("Nasdaq") and delisting from the ASX. Regulatory authorities, the courts, and shareholders would need to approve these changes. The company will also establish **its new headquarters in the United States** effective **January 1, 2027**.

"PhotoCosmetics" as an integral part of the growth strategy

In addition to developing pharmaceuticals, the company is **moving forward with** the launch of a range of non-pharmaceutical consumer products (Non-Rx; OTC), known as **"PhotoCosmetics."** CLINUVEL considers itself 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 aligns with **growing consumer interest** in **scientifically backed products and brands** recommended by dermatologists. In **March 2025 and 2026**, CLINUVEL had a prominent presence at the American Academy of Dermatology (AAD) Meetings in Orlando and Denver, respectively – this is the world's largest dermatology conference. This marked the start **of a two-year pre-launch program** featuring global events, media partnerships, and ambassador programs that position the brand among the top tier of **luxury beauty brands**.

CLINUVEL's innovative skin health brand is targeting a truly massive market

According to McKinsey, the **luxury skincare market will be worth approximately US\$260 billion by CY 2027**; luxury and prestige brands are projected to see the highest growth, with average annual growth rates of 11% and 7%, respectively.

Following the pilot launch of the polychromatic light-stabilizing emulsions **CYACËLLE and CYACËLLE Radiant**, **the market launch is imminent**. The launch of the **second product line** (CLINUVEL Preserve—Assisted DNA Repair) and the **third product line** (CLINUVEL Bronze for self-tanners) is set to follow; preparations do not yet appear to be complete, but an **expected launch in H2 CY 2027** has been advised. The market launch of **CLINUVEL Bronze** is expected to shake up the industry if this **groundbreaking technology from CLINUVEL** succeeds in establishing this **innovative skin health brand**. **The effort is worth it, as management has its sights set on an addressable market of US\$6.2 billion per year.**

We therefore expect the CYACËLLE product line to make a significant contribution to revenue starting from CY 2028 onwards.



SCENESSE® will remain the only approved EPP treatment through at least CY 2027

SCENESSE® from CLINUVEL is the world's first and only approved therapy for the treatment of erythropoietic protoporphyria (EPP) and has been approved by regulatory authorities worldwide (EU 2014; U.S. 2019). **To date, over 21,700 doses have been administered to EPP patients worldwide.** 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 lead a life that would have been unthinkable before treatment.** The SCENESSE® implant is **administered subcutaneously** up to six times a year by physicians who have been specially trained and certified by the manufacturer. It dissolves in the tissue and does not need to be removed.

Erythropoietic protoporphyria (EPP) is an inherited genetic disorder that leads to debilitating phototoxic reactions when patients are exposed to visible light. The **genetic defect that causes EPP cannot be treated at its root.** To prevent symptoms, those affected **currently** have no **choice but to avoid sunlight** and limit their time outdoors. Exposure to light causes painful skin reactions in those affected, often referred to as "light allergy" (**approximately 5,500 EPP patients in the U.S. and the EU combined**).

EMA to Decide in CY 2027 on the Expansion of SCENESSE® (EPP) Approval

CLINUVEL submitted an application to the EMA for an extension of the marketing authorization so that EPP patients in the **older adolescent** age group (**15–17 years**) **can also be treated. Based on their feedback,** the company completed study CUV052 which showed adolescents aged 12 to 17 years experienced similar safety and controlled-release profiles as adult EPP patients. The study results were **submitted to the EMA during FY 2026** and prescribing information and the risk management plan has been updated. **The EMA's decision will be sought with the submission of a revised application in CY 2027.**

We estimate the number of affected adolescent patients in Europe at approximately 150, which **would correspond to a total addressable "adolescent EPP" market of approximately AU\$15 million per year (> €8.5 million).** The CUV052 study will also **support** the expansion of **the U.S. approval** to include 12- to 17-year-olds in the U.S.

SCENESSE® in EPP No competing drug in sight, in our view, before H2/27

SCENESSE® remains the only approved active ingredient (implant) for the treatment of EPP. **Dersimelagon** (an oral MC1R agonist), backed by positive Phase 3 data and currently under review by the FDA, is **on track for potential approval** in late CY2027 or thereafter. **The project was** acquired by the dermatology specialist **LEO Pharma.** **LEO Pharma** acquired the global rights from **Tanabe Pharma** (with a patent expiry date of August 18, 2026) **for up to US\$435 million** (upfront payment + near-term milestones) plus additional milestones and royalties. The FDA accepted the NDA in September and has scheduled the final decision (**PDUFA date**) **for February 2027.** If approved, **it would be the first oral therapy for EPP/XLP.** We **therefore** expect **very strict** requirements and conditions **regarding pharmacovigilance** for **Dersimelagon tablets**, as the risk of off-label misuse is significantly higher with oral treatment than with the subcutaneous implant for SCENESSE®.



Following the FDA's CRL, **Bitopertin** (Disc-1459, an oral GlyT1 inhibitor) has shifted its focus to the **ongoing Phase III APOLLO confirmatory study** (n ≈ 183), with **topline results** expected in **Q4/26**. In our view, a potential FDA decision on the submitted NDA could therefore come around mid-2027. We continue to assume that this treatment, **if at all**, could not reach market readiness **until CY2028**.

Erythropoetischen Protoporphyririe (EPP)	Incidence:	1:140K/ www (ca. 10.000 individuals)
Market (global/USA/EU 5/RoW):		ca. 10k/>2,5K/>2,5k/-
CLINUVEL	Registration:	in EU + in USA; SCENESSE® (16 mg Afa) Implantat
	2014 + 2019	adolescent Study Phase III CUV052
Competition (Company; Product):	Marketing	
Disc Medicine: Bitopertin (Disc-1459)	2028e	oral , once daily in EPP, XP, Phase III APOLLO 3
LEO Pharma: Dersimelagon	2027/ 2028e	oral , once daily in EPP, XLP, 02/27 PDUFA-Date
<i>Source: Companies; PCR - 13.10.2026</i>		

CLINUVEL Chart – EPP

North American Expansion—for EPP and Vitiligo Patients

The focus of regional expansion is on the U.S. and Canada, where multinational pharmaceutical companies have “discovered” this indication—now classified as a “white spot” disease—and aim to treat milder cases with immunomodulators (so-called JAK inhibitors).

The company considers SCENESSE® implants (afamelanotide) to be an alternative to treatment of vitiligo with JAK inhibitors. Certified dermatologists and other specialists with particular experience with the target groups were selected. Since the combination of SCENESSE® and phototherapy is highly effective according to available data, it makes sense to select only those centers that already offer UVA and UVB phototherapy. **A large number of U.S. university and medical centers have already been trained and approved for treatment with SCENESSE® (afamelanotide). The goal is to establish a network of 190 centers** (as of June 30, 2026: 129, including 5 in Canada) **across 48 U.S. states and Canada by the end of 2027**, and to complete this network in the following years. **Billing codes** have been assigned, and **over 100 insurers** are already reimbursing the product.

The network of treatment centers emerging in North America would not only **reach** many of the **estimated 1,300 EPP patients in the U.S.** (approx. 333 million residents) **but** would **also** be able to admit and treat **approximately 6,000 vitiligo patients in the first two years of treatment**. While **continuous annual treatment with up to six SCENESSE® implants** is offered for EPP, repigmentation of 85% to 95% appears possible for vitiligo with 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**.



A Major Opportunity—REPIGMENTATION—SCENESSE® for Vitiligo—For Severe Cases

The current U.S. market for treated vitiligo cases is still relatively small (approximately **US\$200–320 million**), but it has significant growth potential due to new systemic therapies. The large gap between prevalence (1.9–2.8 million people affected) and the number of patients treated (approx. 0.3–0.5 million cases treated annually) explains the high level of interest from pharmaceutical companies. With the market entry of **oral JAK inhibitors** (Rinvoq® already approved in the EU, Litfulo® and others in advanced development) **for mild cases** and potential additional options (e.g., **afamelanotide**) **for severe cases**, significant growth is expected. Analysts and companies estimate a peak sales potential **in the range of several hundred million to the low billions** (depending on market penetration and pricing) for the **U.S. vitiligo indication** with successfully approved systemic therapies (see below).

If vitiligo is an inflammatory response mediated by the JAK-STAT pathway, then JAK inhibitors are precisely what dampen the signal transmission that destroys the pigment-producing melanocytes. It is the same principle that has made JAK inhibitors successful in treating other inflammatory diseases, ranging from rheumatoid arthritis to eczema. **Opzelura® (Incyte Inc)** is expanding its EU indications (AD) and demonstrating sustained long-term efficacy in vitiligo. Its successor, **povorcitinib (Incyte Inc)**, is moving closer to approval for psoriasis and vitiligo. **Rinvoq® (AbbVie)** has received EU approval for vitiligo in July. **Litfulo® (Pfizer)** is delivering strong Phase 3 data for vitiligo and is preparing for global submissions.

However, treatment with JAK inhibitors is essentially an anti-inflammatory approach. In vitiligo, suppressing inflammation prevents the condition from spreading but **does not, on its own, restore melanocytes** (and thus pigment). **This is where combination therapy with SCENESSE® plus radiation (+NB-UVB) comes into play—without suppressing the immune system.**

Furthermore, the **side effects typical of JAK inhibitors** limit their range of applications. **The JAK inhibitor Opzelura® carries a corresponding black box warning in the U.S.** (risks such as severe infections, blood clots, cardiovascular events, certain types of cancer, and increased mortality). **Opzelura® is therefore considered a specialty drug** (prior authorization requirements, safety monitoring, high price of approximately US\$1,900–2,500 per 60-g tube, gross cost per patient: US\$15k–30k+ per year). It is primarily **prescribed by dermatologists and dispensed through a network of specialty pharmacies**, often shipped directly to patients who apply the cream up to twice daily as monotherapy.

The large addressable vitiligo market requires multiple treatment options, depending on severity, skin type, and side effects. **Such cases could benefit particularly well from SCENESSE®, thereby expanding the patient potential addressed by SCENESSE® in the narrower sense to approximately 60,000–65,000 patients in the U.S.** The sought-after approval of SCENESSE® (+NB-UVB) for the treatment of vitiligo targets patients with darker skin tones (Fitzpatrick skin types III–VI) and a larger body area affected by vitiligo, which corresponds to approximately 60,000–65,000 addressable U.S. patients.

JAK Inhibitors – For Mild Cases of Vitiligo, but with a “Black Box Warning”

In the U.S., 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 (approved in the EU since April 2023 as the first and only topical therapy) and is also demonstrating promising efficacy there. Opzelura® continues to grow robustly (underlying double-digit growth),



benefiting from indication expansions (pediatric AD in the U.S., moderate AD in the EU) and the favorable CMS comparison (H1/26: Revenue: +109% YoY to US\$593 million). Strong demand in the U.S. (atopic dermatitis and vitiligo) and growing non-U.S. revenue (including Canada, Italy, and new markets). NICE recommendation in the UK for vitiligo. **Incyte has significantly raised its full-year forecast for Opzelura® (including a one-time CMS effect of US\$ 246 million) to US\$ 1.05–1.10 billion (previously below US\$ 800 million).**

As a successor product, povorcitinib (an oral JAK1 inhibitor) from Incyte Inc. is being successfully tested for vitiligo (NSV), among other indications (positive Phase III data (STOP-V1/STOP-V2); primary endpoint F-VASI75 achieved at Week 52). Regulatory submissions are planned for early 2027.

AbbVie (ABBV/NYSE) is currently testing Rinvoq® (upadacitinib), the oral JAK inhibitor that is already approved for a number of immune-mediated diseases such as RA, PsA, UC, and **vitiligo (NSV)**. Adverse side effects have also led to a “black box warning” in this case. As **the first and so far only systemic therapy, the tablet is approved in the EU** for adult and adolescent **vitiligo patients (NSV)** aged 12 and older (15 mg once daily). **New drug applications (sNDAs)** for both indications (alopecia areata and vitiligo) are currently pending. Decisions regarding vitiligo are expected in the coming months. The new dermatology indications (vitiligo + alopecia areata = circular hair loss) are estimated to reach peak sales of up to US\$2 billion.

Vitiligo	Incidence:	0,5- 2 % www (>40 - 160 Mio. individuals)
Market (global/USA/EU 5/RoW):		<160 Mio./70K/40k/-
CLINUVEL	Registration: 2029e Phase III: CUV105; CUV107 (SCENESSE®; 16 mg Afa dark Skintype (Fitzpatrick-Skintype III-VI) CUV105 Phase III-Topline Results in 12/26; CUV107 Phase III: FPI in 11/26	
Competition (Company; Product):	Marketing	
Incyte Inc: Opzelura (Ruxolitinib)	2022/23	Opzelura (topical JAK-Inhibitor)
Incyte Inc: NCT06113445 (Povorcitinib)	2028e	Povorcitinib (topical JAK1-Inhibitor)
AbbVie: Rinvoq (Upadacitinib)	2027e	Phase III (oral JAK-Inhibitor)
Pfizer: Litfulo (Ritlecitinib)	2028e	Phase III (oral JAK3-Inhibitor)
<i>Source: Companies; PCR - 13.10.2026</i>		

CLINUVEL Chart – Vitiligo

Pfizer (PFE/NYSE) is testing the JAK3 inhibitor Litfulo® (ritlecitinib) for the treatment of NSV. Positive topline results from the Phase III TRANQUILLO and TRANQUILLO 2 studies were published in July 2026. Both doses (50 mg and 100 mg) significantly outperformed placebo on the co-primary endpoints F-VASI75 and T-VASI50 at Week 52. **Global regulatory filings are initially planned for adults.**

Phase III Study CUV107 – Final VITILIGO Registration Study with Highest Priority

CLINUVEL plans to conduct at least two (CUV105 + CUV107) studies that could be relevant for regulatory approval before submitting the regulatory dossier. Following the completion of CUV105, the **Phase III study CUV107 (+NB-UVB; n > 300)** has now **been coordinated with the regulatory authorities, and recruitment is scheduled to begin in Q4/CY26.** Based on the experience from the



CUV105 study (treatment duration, dropout rate), we **do not** expect the earliest potential **market launch before CY 2028, but rather CY 2029.**

Recruitment for the **Phase III CUV105 study for the treatment of vitiligo (n = 210; up to 7 implants + NB-UVB irradiation)** was completed **ahead of schedule in May 2025** following optimization measures. The inclusion criteria for the CUV105 study had been relaxed; nevertheless, most patients must visit the clinic twice a week for up to 18 months to achieve a certain degree of (re)pigmentation. **However**, given the burden of participating in such a clinical program, the **dropout rate for vitiligo is generally quite high. Topline results are expected in December 2026.**

It remains important to note that the CUV study focuses on severe cases involving patients with dark skin types, as this is where the use of SCENESSE® is particularly beneficial. It remains the case that the primary inclusion criterion for **the CUV study is patients with severe disease (>=10% of the body surface area (BSA))**, whereas JAK inhibitors are only suitable 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—sometimes with serious side effects.

If the FDA deems the safety and efficacy data (from approximately 1,000 treatments) from the studies to be sufficient, 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 U.S. (SCENESSE® in EPP).

Based on experience and research findings, CLINUVEL management estimates that a U.S. center **can typically treat 50 new vitiligo patients per year.** Most patients must 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 to achieve about 90% repigmentation over a treatment cycle spanning several years. **However**, given the burden associated with participating in such a clinical program, the **dropout rate for vitiligo is generally quite high**, and patient recruitment is quite challenging.

In summary, CLINUVEL's management expects to be able to treat approximately 6,000 vitiligo patients at 120 U.S. centers in the first few years. Management estimates revenue in the first two years of sales from treating approximately 6,000 patients at **"US\$490 to 570 million" (approx. AU\$691 to 804 million).**

At a potential annual price of >AU\$130k, treating 6k patients with SCENESSE® (planned first phase of the expansion of CLINUVEL treatment centers in the U.S.; approx. 9% of the addressable market) would generate **additional revenue of more than AU\$735 million**, with the **potential** for even higher adoption rates given a larger network (190 centers) of treatment centers.

PHOTOPROTECTION SCENESSE® in VP - CUV053 Phase III trial pending

Variegate porphyria (VP) is a **rare inherited porphyria disorder.** Porphyrins (caused by a deficiency of the enzyme PPOX) accumulate in the liver and can attack the nervous system and the skin, **leading**—typically in adulthood—to the **highly variable symptoms of porphyria attacks.** Affected individuals 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, as well as sensitivity to sunlight, are the most common skin symptoms.

Only CLINUVEL (CUV040; Proof of Concept, Phase IIa, Open-Label Study to Evaluate the Safety and Efficacy of Afamelanotide (16 mg) in Patients with Variegate Porphyria (VP)-Related Skin Disease) has a **targeted drug candidate for VP in the clinical phase.** All six patients reportedly showed positive progress—clinical symptoms were reduced and quality of life improved.

Initial data analyses on systemic photoprotection and dermatological symptoms are still pending. The initial efficacy data will be crucial in determining whether SCENESSE® improves the neurological (abdominal) symptoms and/or the skin symptoms associated with VP. Commencement of **CUV053 as a pivotal Phase III trial has been deferred to give priority to the vitiligo program. The study will be reassessed at a later time. We estimate that it will take about 3–4 years** before SCENESSE® **could be approved** as the second available treatment for VP patients **(as a Type II extension, with 10 years of exclusivity).**

Since 2019/2020, there has been a single therapy approved by the FDA and the EMA called Givlaari (givosiran ALN-AS1) for the treatment of acute hepatic porphyria, including variegate porphyria (VP). In VP specifically, **however, Givlaari addresses only acute symptoms. Givlaari is marketed by Alnylam (NASDAQ: ALNY) in the U.S., the EU, and other countries. The market is small (estimated at approximately 3,000 diagnosed active patients in the U.S. and Europe). Annual revenue in CY25 rose by +20% year-over-year to US\$308 million.** Givlaari is growing steadily and is an important, profitable component of **the rare disease portfolio.** There is currently no major new clinical or regulatory news regarding Givlaari—the focus is on commercial execution and patient expansion.

Variegate Porphyrie (VP)	Incidence:	1:100K/ www (<80.000 individuals)
Markt (global/USA/EU 5/RoW):		<80k/>5K/>5k/-
CLINUVEL OD-Designation (EMA)	Registration: ?	Phase III: CUV053 Start ?
Competition (Company; Product):	Marketing	
Alnylam: Givlaari	2020	akute hepatic porphyrie und VP-patients
-		
<i>Source: Companies; PCR - 13.10.2026</i>		

CLINUVEL Chart - VP

NEURACTHEL®—a generic ACTH for rheumatic and autoimmune diseases

We have **included** the NEURACTHEL® project in our forecast models, as initial revenue could be **generated in the latter part of CY2027.**

Approval for the generic drug **NEURACTHEL® Instant will be sought in a first European filing in H2/CY 26** for the **initial indications. Following initial approval, and other European country filings,** we expect that an **annual** revenue threshold of **US\$ 15 million should be reached some years** thereafter. **In our view, the company's proprietary single-use administration device, ZEROKIN™, will significantly boost patient acceptance—and thus market success.** A modified formulation and



an instant formulation are available. Another goal is to prepare a Drug Master File for submission to the U.S. FDA. **CLINUVEL's** management **estimates NEURACTHEL®'s** standalone revenue potential at approximately **US\$ 150 million** per year (= **AUS\$ 211 million**) within a total addressable market (TAM) of approximately US\$ 1.3 billion.

CLINUVEL is developing NEURACTHEL® Instant as a generic product, meaning that approval requires only demonstration of analytical (human PK testing) and statistical comparability with existing ACTH products from the originator manufacturers—which **entails** less time, less money, and **less risk**. **Since January 2023, production of NEURACTHEL® has been continuously scaled up to commercial levels in accordance with cGMP standards** (for both the active ingredient and the finished drug product) **in collaboration with the partner**. In addition to quality, **manufacturing costs** are a key aspect of optimization efforts for generic drug manufacturers.

Just in time for **the first registration in an EU country**, CLINUVEL has completed the development of ZEROKIN™, a **proprietary single use administration device for subcutaneous drug administration**. ZEROKIN™ is used to administer novel controlled-release formulations developed at CLINUVEL's research, development, and innovation center in Singapore (**RD&I** center VALLAURIX). It will be registered with the FDA as a Class II device via the 510(k) notification and must obtain a CE mark in accordance with the EU Medical Devices Regulation.

We certainly see the economic potential—the **ACTH market** (approved by the FDA for 24 indications) **is estimated to reach US\$933 million annually (>+39% YoY) across all therapeutic areas by CY 2025**. A significant portion of this is attributable to **MS relapses**.

As a treatment, ACTH is an alternative to corticosteroids (prednisone, etc.) used to treat rheumatic and autoimmune diseases. Like corticostroids, ACTH does not slow the progression of the disease. ACTH was first approved as a therapeutic agent in **the 1950s**. ACTH analogs are available as liquid and gel formulations—for injection, ideally using a **self-injection device**—for use in severe chronic and acute neurological, endocrinological, and degenerative diseases.

H.P. Acthar Gel has long been used off-label to treat **seizures in children (approximately 1,800–2,200 new cases per year in the U.S.)**. **P. Acthar Gel** was originally approved in 1952. For Mallinckrodt Pharmaceutical plc (NYSE: MNK), **Acthar Gel is the main revenue driver, generating US\$ 644 million (+40% YoY)**. Acthar Gel's growth in 2025 was primarily driven by higher demand, in tandem with the strong resurgence of the overall ACTH market. The **self-injection device**, approved in CY2024, **was the key driver of this growth**. In Q3/2025, for example, 84% of all new prescriptions were for Selfject. The device makes administration significantly easier and more patient-friendly.

ANI Pharmaceuticals (NASDAQ: ANIP) received **FDA approval for Cortrophin Gel in November 2021**. The company has been expanding for years into additional applications and indications. Like H.P. Acthar, the drug is **approved for chronic (22) autoimmune diseases**, including MS, rheumatoid arthritis (RA), and nephrotic syndrome (NS). **By fiscal year 2025—four years after its market launch—sales of Cortrophin Gel had risen to nearly US\$348 million (+76% year-over-year)**. Thanks to expanded indications (particularly in neurology) and intensified sales efforts, the product was the clear growth





driver for ANI Pharmaceuticals and accounted for a large portion of rare disease sales. The guidance for FY26 calls for US\$520 million.

NEURACTHEL® ACTH-Generic	Incidence:	24 indications
Markt (global/USA/EU 5/RoW):		>US\$ 900 m/-
CLINUVEL	Registration:	EU Filings CY26e; ACTH generic, liquid
	2027e	NEURACTHEL® Instant in IS, MS
Competition (Company; Product):	Marketing	
Mallinckrodt: H.P. Acthar Gel	2014	chronical autoimmune disease (MS,RA,NS, etc.)
ANI Pharmaceuticals: Cortrophin Gel	2022	chronical autoimmune disease (MS,RA,NS, etc.)
<i>Source: Companies; PCR - 13.10.2026</i>		

CLINUVEL Chart - Generic ACTH



FINANCE

FY 2025/2026 (abbreviated: FY2026) – Disciplined Consolidation and Targeted Expansion

The financial results reflect the company's disciplined strategy, which is based on continuous improvement and strict cost control and creates a solid foundation for diversification and future revenue streams through the ongoing progress of the clinical portfolio. The expansion of operations (infrastructure, capacity, and U.S. presence) is in line with the long-term strategy and the increased focus on North America.

The company reports its financial results in accordance with Australian accounting standards. **Total revenue (TR)**, including interest and other income—the most important top-line KPI—amounted to AU\$ 101.2 million in FY 2026, representing a **decrease** of AU\$ 4.1 million, or 4%, compared to the previous year (FY 2025: AU\$ 105.3 million). **Net sales** (commercial and Special Access Scheme) totaled AU\$ 94.0 million (–1% YoY compared to AU\$ 95.0 million). **Despite the slight decline, record treatment volumes** were achieved with SCENESSE® (global +6%, Europe +13%).

Total expenses remained virtually stable at AU\$ 53.5 million (–0.5% YoY compared to AU\$ 53.7 million), underscoring the company's continued strict cost discipline. The company continued its planned expansion and exceeded the target of 120 trained and certified specialty centers in North America (currently 134 centers). The network is being **prepared for future vitiligo care** and is set to expand to 190 centers by the end of 2027. Expenditures were closely aligned with strategic objectives. The focus was on **further developing the pipeline** (particularly the Phase III vitiligo program CUV105, preparations for CUV107, and NEURACTHEL®) as well as expanding the U.S. infrastructure and the VALLAURIX RD&I center in Singapore.

Cash reserves (cash and time deposits) **increased by AU\$ 28 million (+12% YoY) to AU\$ 252.1 million** (excluding the AU\$12.2 million advance payment of income tax, the figure would have been AU\$ 264 million). This continues to provide room for organic expansion, pipeline development, and potential M&A activities. The company continued to benefit from interest income on time deposits.

For FY 2026, the company reported on August 27, 2026, a net profit before taxes of AU\$ 47.7 million (–8% YoY compared to AU\$ 51.6 million) and a net profit after taxes of AU\$ 33.9 million (–6% YoY compared to AU\$ 36.2 million). Basic EPS was AU\$ 0.68 (previous year: AU\$ 0.72). With this, CLINUVEL achieved its **tenth consecutive annual profit** and has paid its **ninth consecutive dividend** (AU\$ 0.05 per share).

The **balance sheet remained very solid**: Net assets rose to AU\$ 272.9 million (+13% YoY), and total assets to AU\$ 295.1 million. The company has been debt-free for the 20th consecutive year. Operating cash flows amounted to approximately AU\$ 37–40 million and were primarily driven by global SCENESSE® revenues.

The **expansion of the VALLAURIX RD&I Center** is taking on increasing importance. In December 2025, CLINUVEL announced a significant **five-year expansion** of the VALLAURIX Center, supported by the Singapore Economic Development Board (EDB): The current focus is on expanding formulation and analytical capabilities—including the construction of additional state-of-the-art laboratories and the gradual increase in the number of specialists on staff. The goal is to achieve **full commissioning** and



certification of the expanded facilities by **FY2028**. The expansion is not expected to disrupt ongoing programs (e.g., vitiligo, NEURACTHEL) and will strengthen CLINUVEL's vertical integration.

The center serves as the central hub for the **development of new peptide formulations and drug delivery platforms** (particularly controlled-release/long-acting systems for melanocortins and other peptides). Development efforts are focused on liquid controlled-release/long-acting drug delivery platforms ("VLRX-L platform"). Candidates of this type, with superior release profiles, were identified several months ago. Optimization is currently underway at the site; additional **preclinical studies are planned for Q1/27**; and preparations for a manufacturing scale-up are also underway.

PCR Estimates for FY 2027 and FY 2028 - Revenue and OPEX Modeling

The company has not issued any guidance.

CLINUVEL remains in investment mode to pursue diversification. Plans include the launch of CUV107 (H2/CY26), full CUV105 results (H1/CY27), the PhotoCosmetics launch (M-lines Preserve and Bronze in H2/CY27), and the continued **expansion of its U.S. presence and RD&I center in Singapore**. Revenue streams are expected to become increasingly diversified through vitiligo (TAM > US\$ 4.5 billion), NEURACTHEL® (TAM ~ US\$ 1.3 billion), and other programs. The strong cash position enables self-financed implementation without dilution. The company has thus further strengthened the foundation for its **transition from a single-product to a multi-product company** and is clearly positioning itself for the **North American market as its future focus**.

We estimate that product revenue (excluding interest income) will grow by 3% initially and then by 17% (nominally) in FY 2027 and FY 2028, as regional expansion (EPP in the U.S.) and indication expansions for SCENESSE® in EPP (label alignment between the EU and the U.S.; for adolescents in the EU) are achieved and fully implemented. We estimate risk-adjusted revenue for FY 2027 and FY 2028 to be AU\$ 85.6 million (-9% year-on-year) and AU\$ 87.8 million (+2.6% year-on-year).

We expect **gross interest income** for both years to be at a level similar to that in FY26 (AUS\$ 10.44 million)

In our view, the **R&D ratio** will **rise** in FY 2027e and FY 2028e, as we anticipate that the **key Phase III clinical vitiligo program CUV107, as well as the evaluation of CUV105**, will be conducted during this period. In our view, the highly efficient in-house execution of clinical trial programs (compared to full outsourcing to CRO service providers) will keep the increase in costs manageable in absolute terms.

The **manufacturing supply chain** is to be better integrated, which could be further implemented by expanding internal capabilities or through strategic acquisitions. The reduction in headcount — as previously announced — will also have an impact here, which will be quite noticeable at first.

Administrative expenses are likely to rise, particularly in FY27, if the Executive Board's planned organizational, legal, and capital market initiatives — key points here being **a full Nasdaq listing**, a change of company name, and the relocation of the company's headquarters to the U.S. — are implemented.



With the market launch of the three OTC products in the “PROTECT” sun protection and skincare line, we expect an **above-average increase** in the “Communications and Marketing” line item on the income statement by the end of the period. **The continued expansion of the network of treatment centres in the U.S. and Canada is likely to be reflected in this line item as early as FY27.**

CLINUVEL - revenue forecast by indication				in AU\$ m; last column: total 2027e-2030e			
	2025	2026	2027e	2028e	2029e	2030e	27e-30e
Revenue (unweighted)							
Total	95.0	94.0	96.3	109.0	142.1	211.6	559.0
SCENESSE® EPP (adults)	95.0	94.0	93.8	98.5	106.9	118.8	418.0
SCENESSE® EPP (adolescents)	0.0	0.0	0.1	0.3	1.5	2.5	4.3
SCENESSE® XP	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SCENESSE® VP	0.0	0.0	0.0	0.5	4.5	9.0	14.0
SCENESSE® vitiligo	0.0	0.0	0.0	0.0	10.7	53.4	64.0
NEURACTHEL® ACTH generic (MS etc.)	0.0	0.0	2.3	7.8	15.6	23.4	49.1
PRÉNUMBRA® stroke (AIS)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PhotoCosmetics	0.0	0.0	0.2	2.0	2.9	4.5	9.6
Risk-adjusted revenue							
Total	95.0	94.0	85.6	87.8	103.0	136.8	413.3
SCENESSE® EPP (adults)	95.0	94.0	83.4	79.7	78.6	79.5	321.2
SCENESSE® EPP (adolescents)	0.0	0.0	0.0	0.2	1.1	1.6	2.9
SCENESSE® XP	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SCENESSE® VP	0.0	0.0	0.0	0.3	3.1	5.5	8.9
SCENESSE® vitiligo	0.0	0.0	0.0	0.0	7.4	33.0	40.4
NEURACTHEL® ACTH generic (MS etc.)	0.0	0.0	2.0	6.1	10.8	14.5	33.4
PRÉNUMBRA® stroke (AIS)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PhotoCosmetics	0.0	0.0	0.1	1.6	2.0	2.8	6.6
Probability of approval (Tufts/DiMasi)							
Phase I	13%						
Phase II	21%						
Phase III	61%						
Submission for approval	90%						
Probability that a clinical candidate in the respective phase is approved							

Source: Company information; PCR estimates (as of 13 October 2026)

CLINUVEL Chart - Revenue



In our modeling, the income tax rate remains stable at approximately 32% of EBT during the detailed planning phase. The **EPS KPI will rise between FY 2027 and FY 2028 in line with net income**, as we **do not** anticipate **any significant capital increases**.

DCF Model

Our EAT analysis takes organic growth (excluding acquisitions) into account. We expect growth to accelerate again in FY 2027 and FY 2028 (compared to FY 2026) (see above).

After the detailed planning phase (through FY 2028), the expected growth rate in the DCF calculation declines to **11% per annum, which is likely a conservative assumption given the company's plans**. We 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% and is based on the company's historical performance (+ risk premium). This results in a rounded **weighted average cost of capital (WACC) of approximately 8.55%** as the basis for the discount factor.

Using the method described, the DCF valuation yields an enterprise value of **AU\$ 14.79 (previously: AU\$ 23.94 per share)**.

CLINUVEL Pharmaceuticals Ltd. - DCF model										in AU\$ m
	2026	2027e	2028e	2029e	2030e	2031e	2032e	2033e	2034e	2035e
	Phase I: detailed forecast			Phase II: expansion					Phase III	
Earnings after tax (EAT)	33.91	29.97	30.84	34.20	38.31	42.90	48.05	53.82	60.28	67.51
Discounting period (years)	-0.27	0.73	1.73	2.73	3.73	4.73	5.73	6.73	7.73	7.74
Growth-adj. current yield	2.63%	2.63%	2.63%	2.63%	2.63%	2.63%	2.63%	2.63%	2.63%	2.63%
Company-specific risk premium	5.93%	5.93%	5.93%	5.93%	5.93%	5.93%	5.93%	5.93%	5.93%	5.93%
EAT growth, stable phase										1.00%
Discount rate		8.55%	8.55%	8.55%	8.55%	8.55%	8.55%	8.55%	8.55%	7.55%
Discount factor		0.94	0.87	0.80	0.74	0.68	0.62	0.58	0.53	7.536
Present value	33.91	28.23	26.77	27.34	28.21	29.11	30.03	30.98	31.97	508.76

Enterprise value (AU\$ m)		Per-share valuation	
Phase I (2026 - 2028e)	88.91	Fair value per share (AU\$)	14.79
Phase II (2029e - 2034e)	177.64	Current share price (AU\$)	7.77
Phase III (terminal value from 2035e)	508.76	Price potential	90.36%
Total enterprise value	741.40	Current market value (AU\$ m)	391.82
EAT CAGR Phase II	12.0%	Discount rate (WACC)	8.55%

Blended valuation (85% : 15%; DCF : EV/EBIT)	Value per share (AU\$)	Weight	Contribution (AU\$)
DCF	14.79	85%	12.57
EV/EBIT (FY 2027e)	12.08	15%	1.81
Blended fair value			14.38

Source: Company information; PCR (as of 13 October 2026)

CLINUVEL Chart - DCF Model



CUVL on the Nasdaq – Considerations Regarding a Full U.S. Listing and Delisting from the ASX

In addition to regulatory approvals in Europe, we view a **full listing on the Nasdaq as the next growth catalyst**. In the short term, however, we expect some uncertainty among shareholders.

According to its own statement (CN 08/27/26), the Executive Board is considering changing CLINUVEL's corporate holding structure, seeking a listing of its common stock on the Nasdaq Stock Market ("Nasdaq"), and delisting from the **ASX and the Frankfurt Stock Exchange (FWB)**.

The process is subject to an ongoing due diligence review and the final approval of the Executive Board. The transaction would be carried out by way of a **"scheme of arrangement"** pursuant to Part 5.1 of the Corporations Act 2001 (Cth), which would be subject to **shareholder approval (at the Annual General Meeting)**. As part of the transaction, a foreign holding company ("New HoldCo") would become the new parent company of the CLINUVEL Group. CLINUVEL's current shareholders would receive common shares of New HoldCo representing an economic interest proportional to their existing ownership interest in CLINUVEL (subject to the rounding of fractional entitlements). New HoldCo would seek a listing on the Nasdaq (Global Select Market).

Biotech stocks are among the investments with the highest investment risks, which is particularly true for young startups that typically require capital over several years but do not yet have a market-ready product. **CLINUVEL, on the other hand, has been profitable for ten years**, has no debt, and holds free cash of AU\$ 252 million (market capitalization of approximately AU\$ 390 million); **in our view, it is on the verge of a growth spurt**. In short, this is a business model with a highly sought-after risk-reward, as the history of many index heavyweights on the **Nasdaq Biotechnology™ Index** clearly demonstrates. **These heavyweights include well-known names such as Amgen, Gilead Sciences, Regeneron Pharma, and Vertex Pharmaceutical**—all prominent drug developers that draw significant investor attention to the biotech sector. The total market capitalization of **the Nasdaq Biotechnology™ Index (NBI)**, with its more than 250 constituents, now stands at **approximately US\$1,220 billion**.

This considered move reflects the growing importance **of CLINUVEL's U.S. shareholder base**. CLINUVEL's visibility in the U.S., market access, and the **engagement of key institutional investors will be further enhanced by the full listing**.

While less than 20% **of shares** were held **by institutional investors** in 2019, according to the FY 2025 annual report, this figure had risen to approximately **34%**. CUV has approximately 70% foreign investors, with about 30% coming from Australia. The home stock exchange is the Australian Securities Exchange (ASX), where CLINUVEL's stock is listed in the **S&P/ASX 300 and the ASX All Ordinaries (498 stocks)**, among others; its market capitalization is significantly lower than that of unprofitable biotechs listed in the U.S. The largest company on the index, with a market capitalization of just over AU\$ 84 billion, is the plasma and vaccine manufacturer **CSL Limited**. In our view, **therapeutic developers** and biotech companies do not play a prominent role in the index. Given the limited commercial and capital market significance of the pharmaceutical and biotech segment on the ASX index, the Board is considering a full Nasdaq listing and delisting from the ASX to improve access to investors and valuation on the world's largest stock market.



VALUATION

Summary of the Valuation

The positive progress prompted us as early as May to assign a higher weight to company-specific factors in the valuation mix (**new: 85:15%**; old: 75:25%).

In our view, the **regulatory prospects** for the CUV 107 landmark Phase III study on vitiligo in the EU have **improved significantly** when assessed using a “total evidence” approach.

We **therefore tend to view** the likelihood of **EMA approval (in the second half of 2026: first data from the CUV105 Phase III trial in Dec. 2026; start of the CUV107 Phase III trial in Nov. 2026) as higher, even if it requires more time.**

The market is primarily focused on the **risk-reward profile of the planned approval (~CY 2029) of SCENESSE®** for the treatment of **vitiligo** as the largest potential growth driver.

Taking into account the updated development plans and estimates, the risk-reward ratio has deteriorated. We currently set the price target at **AU\$14.50** (previously: AU\$25.00), which remains well above the current share price.

We reaffirm our BUY recommendation for the shares of CLINUVEL Pharmaceuticals Ltd.



FINANCIAL KEY FIGURES

P&L (in AU\$m)	2025	2026	2027e	2028e	2029e
Revenues	95.018	94.024	85.620	87.840	103.021
Total costs of revenue	-14.813	-15.814	-12.240	-12.558	-15.464
Gross margin	80.204	78.211	73.380	75.282	87.557
Research & Development	-20.701	-18.091	-18.451	-19.876	-24.476
General and administrative	-9.348	-11.172	-14.208	-13.306	-14.045
Communication and marketing	-8.885	-8.416	-7.280	-7.842	-10.118
Income from operations (EBIT)	41.270	40.532	33.441	34.258	38.918
Interest income	10.258	6.483	10.625	11.090	11.373
Other income	0.024	0.645	0.000	0.000	0.000
EBT	51.553	47.660	44.065	45.348	50.291
Taxes	-15.380	-13.743	-14.099	-14.509	-16.091
Net income before minorities	36.173	33.917	29.967	30.839	34.200
Minorities	0.000	0.000	0.000	0.000	0.000
Net income	36.173	33.917	29.967	30.839	34.200
Adjustements	-0.024	-0.645	0.000	0.000	0.000
Net income (adjusted)	36.148	33.272	29.967	30.839	34.200
Number of shares	50.120	50.120	50.120	50.120	50.120
Number of shares (diluted)	50.120	50.120	50.120	50.120	50.120
EPS	0.722	0.677	0.598	0.615	0.682
EPS, adjusted	0.72	0.66	0.60	0.62	0.68
EPS, diluted	0.72	0.68	0.60	0.62	0.68
EPS, diluted and adjusted	0.72	0.66	0.60	0.62	0.68
DPS	0.05	0.05	0.05	0.05	0.06

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

Cash flow statement (in million AU\$s)	2025	2026	2027e	2028e	2029e
Cash flow from operating activities	41.10	36.91	33.00	31.74	32.40
Cash flow from investing activities	-0.299	-1.603	-1.459	-1.459	-1.459
Cash flow from financing activities	-50.356	-40.273	-2.506	-2.257	-2.323
Change in cash and cash equivalents	-9.559	-4.966	29.038	28.026	28.615
Cash and cash equiv. end of the period	28.021	21.392	50.430	78.456	107.071

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



Balance sheet (in million AU\$)	2025	2026	2027e	2028e	2029e
<i>Fixed assets</i>	<i>203.397</i>	<i>240.094</i>	<i>240.402</i>	<i>240.459</i>	<i>240.316</i>
Intangible assets	0.591	2.138	2.138	2.138	2.138
Property, plant and equipment	6.721	7.293	7.600	7.657	7.515
Financial assets	196.085	230.664	230.664	230.664	230.664
<i>Current assets</i>	<i>66.884</i>	<i>53.967</i>	<i>80.294</i>	<i>109.036</i>	<i>142.549</i>
Inventories	8.821	6.881	6.266	6.429	7.540
Trade receivables	27.461	23.454	21.357	21.911	25.698
Other receivables	2.581	2.240	2.240	2.240	2.240
Cash and securities	28.021	21.392	50.430	78.456	107.071
Other assets	1.469	1.030	1.030	1.030	1.030
Total assets	271.750	295.091	321.725	350.525	383.895
<i>Shareholders' equity</i>	<i>240.809</i>	<i>272.881</i>	<i>300.342</i>	<i>328.923</i>	<i>360.801</i>
Reserves	240.809	272.881	300.342	328.923	360.801
Minority interests	0.000	0.000	0.000	0.000	0.000
<i>Accrued liabilities</i>	<i>2.501</i>	<i>3.123</i>	<i>3.123</i>	<i>3.123</i>	<i>3.123</i>
<i>Accounts payable</i>	<i>25.020</i>	<i>17.899</i>	<i>17.072</i>	<i>17.291</i>	<i>18.783</i>
Interest-bearing liabilities	0.529	1.938	1.938	1.938	1.938
Liabilities from trade payables	9.945	9.246	8.419	8.638	10.131
Other non-interest-bearing liabilities	14.547	6.714	6.714	6.714	6.714
<i>Other liabilities Other liabilities</i>	<i>3.420</i>	<i>1.188</i>	<i>1.188</i>	<i>1.188</i>	<i>1.188</i>
Total liabilities	271.750	295.091	321.725	350.525	383.895

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



Overview of key figures	2025	2026	2027e	2028e	2029e
Key valuation figures					
EV/Sales	6.57	5.12	4.31	4.20	3.58
EV/EBITDA	14.69	11.60	10.66	10.34	9.10
EV/EBIT	15.12	11.89	11.03	10.77	9.48
P/E RATIO	18.02	15.06	13.00	12.63	11.39
Price/book value	2.706	1.837	1.297	1.184	1.079
Profitability ratios in %					
Gross margin	84.4%	83.2%	85.7%	85.7%	85.0%
EBITDA margin	44.7%	44.2%	40.4%	40.6%	39.3%
EBIT margin	43.4%	43.1%	39.1%	39.0%	37.8%
Pre-tax margin	54.3%	50.7%	51.5%	51.6%	48.8%
Net margin	38.1%	36.1%	35.0%	35.1%	33.2%
ROE	30.0%	13.0%	10.5%	9.8%	9.9%
Key productivity figures					
Turnover/employee (in AU\$ thousand)	819	940	1,007	945	1,010
Net revenue/employee (in AU\$ thousand)	312	333	353	332	335
Number of employees	116	100	85	93	102
Key financial figures					
Equity ratio	88.6%	92.5%	93.4%	93.8%	94.0%
Dividend yield	0.4%	0.5%	0.6%	0.6%	0.7%
Other key figures					
Working capital/sales (in %)	27.7%	22.4%	22.4%	22.4%	22.4%
Tax rate (in %)	29.8%	28.8%	32.0%	32.0%	32.0%
<i>Source: PCR</i>					



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Company	Analysts	Date	Recommendation / Price Target
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	September 9, 2024	Buy / AU\$ 26.10
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	February 10, 2025	Buy/AU\$ 19.27
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	March 7, 2025	Buy/AU\$ 22.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	June 26, 2025	Buy/AU\$ 22.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	September 30, 2025	Buy/AU\$ 26.50
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	March 25, 2026	Buy/AU\$ 24.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	May 27, 2026	Buy/AU\$ 25.00
CLINUVEL Pharmaceuticals	T. Schiessle; D. Grossjohann	October 14, 2026	Buy/AU\$ 14.50

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