

## Clinuvel

Reuters: CUV.AX

Bloomberg: CUV:AU

### The light protection enabler

We're initiating coverage of Australian Clinuvel with a buy rating and a price target of AUD 31.70 per share, since we believe investors are not fully factoring in potential opportunities to Clinuvel's long-term growth in the global skin protection market. The orphan disease drug company is dramatically expanding top-line growth in the near-term as we expect the company to expand its global footprint in EPP. Apart from these significant growth opportunities, that even a rare disease like EPP offers, we expect even more in the years to come, since (1) Clinuvel is expected to launch its vitiligo product in 2021e, representing a substantial larger market than the rare disease EPP, (2) the launch of a topical product should make room for the mass market of non-prescription skin care solutions, and (3) Clinuvel could also offer a treatment for various Central Nervous System disorders among them MS, dementia, Alzheimer's, Parkinson's, ALS, or Huntington's. Apart from EPP, none of these growth opportunities have so far been factored in into our company valuation, leaving substantial upside to our price target in the long-term.

#### Core product afamelanotide

Clinuvel's afamelanotide drug called "Scenesse" is the only viable treatment option for erythropoietic protoporphyria (EPP), a rare genetic disorder which causes severe anaphylactoid reactions and burns (phototoxicity) following even brief exposure to visible light, both of artificial and natural light sources. With a global prevalence to be estimated somewhere between 1:75,000 and 1:200,000, an estimated 25,000-67,000 people suffer from EPP worldwide. According to our estimates, only ~265 patients were treated in 2017 by Clinuvel, leaving substantial upside.

#### Short- and medium-term forecast

With revenues of AUD 17.0 mn (+164.6% YoY), Clinuvel reported operating profits of AUD 7.1 mn and positive free cashflows for the first time in company history in 2016/17 (30/06). With a substantially raising number of EPP patients treated by Scenesse, group revenues should improve to AUD 46.4 mn in 2017/18e (+172.8% YoY), according to our estimates Operating profits are expected to triple to AUD 22.5 mn. In the medium-term (2020/21e), we expect revenues and EBIT to increase to AUD 409.1 mn and AUD 243.5 mn, respectively. This is equivalent to a revenue CAGR 2016/17-2021e of 121.5%.

#### DCF based equity value AUD 31.70 per share (base case)

From our three stage DCF entity model, we calculate an equity value of AUD 31.70 per share (base-case scenario); bear and bull case scenario equity values from a Monte Carlo simulation are AUD 25.90 and AUD 43.00 respectively. Our quantitative modelling of EPP shows a significant value upside even if certain parameters should not perform as expected.

Our valuation is based solely on the treatment of EPP. Vitiligo as well as topical or neurodegenerative disease represent substantial long-term upside.

Rating: Buy Risk: High

Price: AUD 8.65

Price target: AUD 31.70

WKN/ISIN: A0JEGY/AU000000CUV3

Indices: All Ordinaries Index (XAO)

Transparency level: n/a

Weighted average number of share: 47.7 mn

Market cap: AUD 412.9 mn

Daily trading volume: ~40,000 shares

Next AGM: n/a

AUD mn (31/12)	2016	2017	2018e	2019e
Revenues	6.4	17.0	46.3	133.4
EBITDA	-3.1	7.2	22.7	72.0
EBIT	-3.2	7.1	22.5	71.6
EBT	-3.2	7.1	22.8	72.0
EAT	-3.2	7.1	22.8	72.0

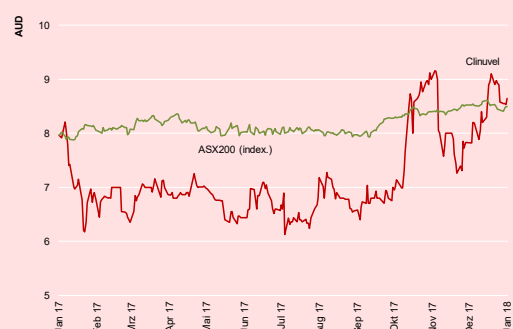
% of revenues.	2016	2017	2018e	2019e
EBITDA	-48.7	42.2	48.9	54.0
EBIT	-49.1	41.9	48.6	53.7
EBT	-49.1	41.9	49.1	54.0
EAT	-49.1	41.9	49.1	54.0

Per share (AUD)	2016	2017	2018e	2019e
EPS	-0.07	0.15	0.48	1.51
Dividend	0.00	0.00	0.00	0.00
BVPS	0.39	0.53	1.01	2.52
CFPS	-0.11	0.21	0.44	1.38

%	2016	2017	2018e	2019e
Equity ratio	89%	89%	85%	83%
Gearing	-78%	-93%	-92%	-90%

X	2016	2017	2018e	2019e
P/ER	n/a	47.2	18.1	5.7
EV/sales	28.3	18.2	8.0	2.3
EV/EBITDA	n/a	43.4	16.4	4.2
P/BR	11.0	13.1	8.6	3.4

AUD mn	2018e	2019e
Guidance: Revenues	n/a	n/a
Guidance: EBIT	n/a	n/a



SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

Peter-Thilo Hasler, CEFA

+ 49 (89) 74443558 / +49 (152) 31764553

peter-thilo.hasler@sphene-capital.de

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**Please note that each chapter begins with an extensive executive summary.**

## Executive Summary

### **EPP is a rare disease with a prevalence between 1:75,000 and 1:200,000**

Clinuvel's lead compound, afamelanotide (distributed under the brand "Scenesse") is the first and only systemic photoprotectant drug for the prevention of phototoxicity in adult patients with erythropoietic protoporphyria (EPP). EPP is a genetic disorder, resulting in the accumulation of compounds ("porphyrins") in various tissues. After exposure to light, EPP patients suffer from burning, swelling, and itching of the skin, edema, persistent redness or inflammation, second degree burn and anaphylactoid reactions; some even develop more advanced liver disease. Since the photosensitivity results from light in the visual spectrum (400 to 700 nm) as well as UV, window glass does not offer protection from wavelengths. Even hypersensitivity to artificial light is common. EPP patients spend a considerable amount of time avoiding all sources of light. Therefore, suicide rates are high among EPP patients.

### **Clinuvel's EPP solution Scenesse**

Delivered via a subcutaneous dissolving implant in the iliac crest of the hip, Scenesse increases the melanin content of the skin without exposure of the skin to the damaging effects of UVR. Results of more than 20 clinical studies were impressive, with pain scores significantly lower and light tolerance substantially higher in patients receiving Scenesse compared to those receiving the placebo. Therefore, Clinuvel has obtained EMA authorisation under exceptional circumstances in 2014 and a gradual roll-out per country has been pursued.

### **Financial forecast**

With estimated approximately 265 patients treated with Scenesse, mainly in the Netherlands, Switzerland, and Germany, Clinuvel reported revenues of AUD 17.0 mn in 2016/17 (30/06), significantly above prior year's levels of AUD 6.4 mn (+164.6% YoY). With AUD 7.1 mn and EBIT margins of 41.9%, the company reported operating profits for the first time in company history. Free cashflow was AUD 9.8 mn, since reinvestment needs are negligible. In the coming years, we expect substantial revenue, earnings and cashflow growth rates. Based on our forecasts, we have modelled average annual revenue growth rates 2016/17-20/21e of 121.5%, since we expect Scenesse to become the de facto standard treatment for EPP. At the end of our planning period in 2020/21e, revenues and EBIT should improve to AUD 409.1 mn and AUD 243.5 mn, respectively (which is equivalent with EBIT margins of 59.5%). In 2021e, we expect Clinuvel to receive EMA and FDA approval for its vitiligo treatment which will offer Clinuvel a substantial larger market than orphan disease EPP. Beyond 2021e, the launch of a topical product should be a further option, making room for medical prescription products (e.g. DNA repair), as well as for mass market non-prescription skin care solutions, (e.g. self-tanning skin lotions).

### **Price target of AUD 31.70 per share vs. current share price of AUD 8.65**

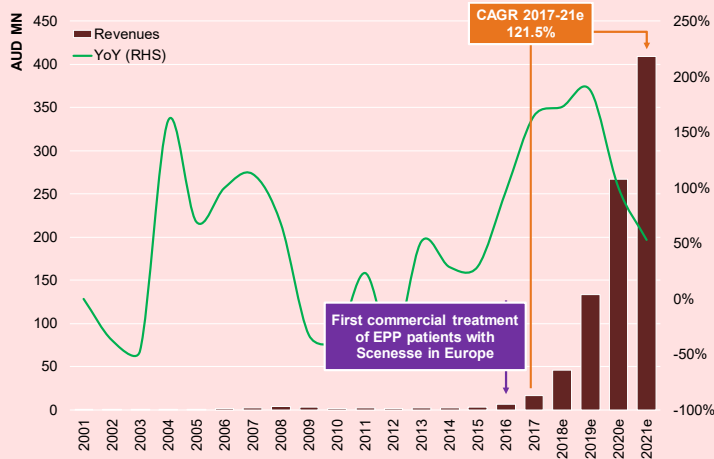
Our valuation methodology for Clinuvel is a three-stage DCF entity model which captures best the huge long-term potential of the highly profitable EPP niche market, in our view. Calculating WACC of 14.5%, revenues CAGR of 121.5% during the detailed planning phase 2016/17-20/21e and of 5.1% during the rough planning phase (2021/22e-31/32e, we figure an equity value of AUD 1,490.8 mn (base-case scenario). 21.5% of that value is derived from the terminal value, 18.3% from cash flows generated in the detailed planning phase 2016/17-20/21e and 60.2% from cash flows generated in the rough planning phase 2021/22e-31/32e. Adding net cash, this results in an equity value of AUD 31.70 per share. From a Monte Carlo simulation, we calculate bear and bull case scenario values of AUD 25.90 and AUD 43.00 per share, respectively.

### **Weaknesses and risks**

The primary risk to our price target is Clinuvel's sub-standard investor relations policy that does not suit a company of this size or reputation, in our view. Not only does the management refrain from providing standard shareholder services such as working subscription link connections on its website, even contact data to the investor relations manager will not be given to interested parties. In addition, the company's reporting is opaque with respect to certain aspects highly relevant for an independent company valuation (further details see p. 25).

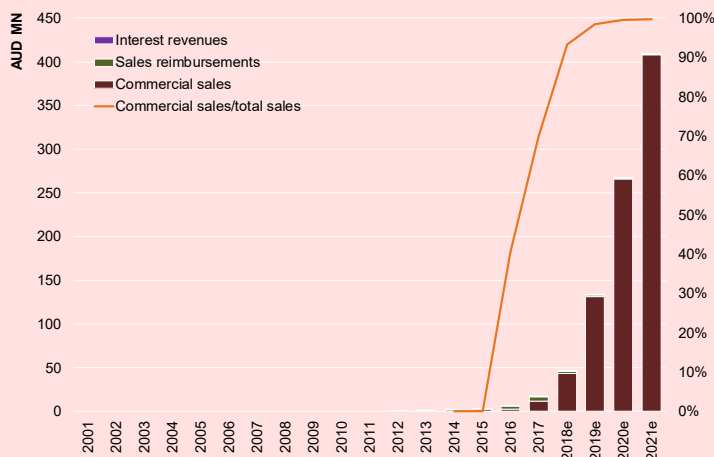
## Business profile

### REVENUES AND REVENUE GROWTH



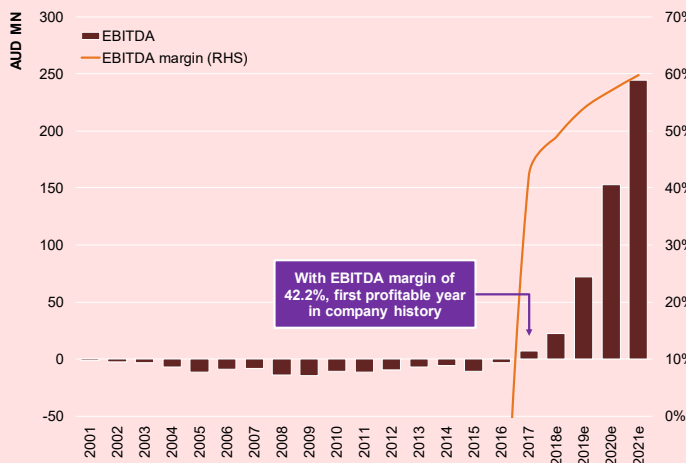
We expect compound annual revenue growth rates of 121.5% for the period of 2016/17e-20/21e. In total, we expect group revenues of AUD 409.1 mn in 2020/21e, up from AUD 17.0 mn in 2016/17. We estimate that Clinuvel treated 265 EPP patients in the last fiscal year. Being the only treatment against EPP, total number of patients will substantially increase: We expect Clinuvel to treat 3,724 patients (CAGR 2016/17-20/21e 93.6%) by the year 2020/21e.

### REVENUES BY SEGMENTS



Our company growth forecast is based on a mix of domestic and international growth. In Europe, we project an average annual growth rate of 82.1% during our 2016/17-20/21e forecast period. Revenues in the US should speed up when FDA approval has been obtained, which we expect to happen during the current year 2018e.

### EBITDA AND EBITDA MARGIN

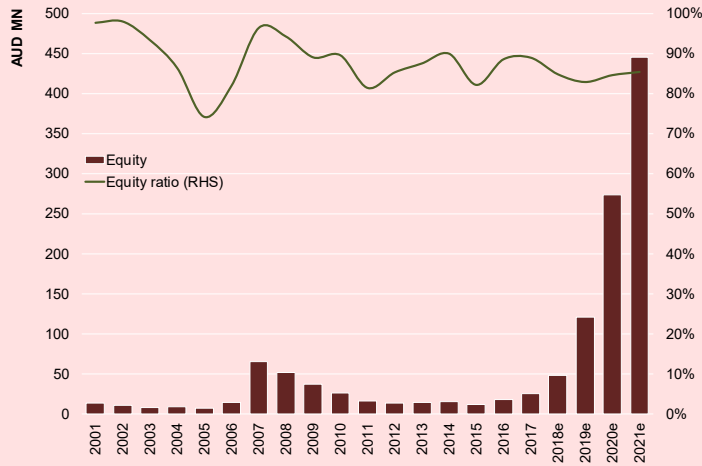


Following a significant decline in R&D, commercialization and general expenses, EBITDA is expected to substantially increase over our planning horizon. For 2020/21e, we expect EBITDA of AUD 244.8 mn, corresponding to EBITDA margins of 59.8%.

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

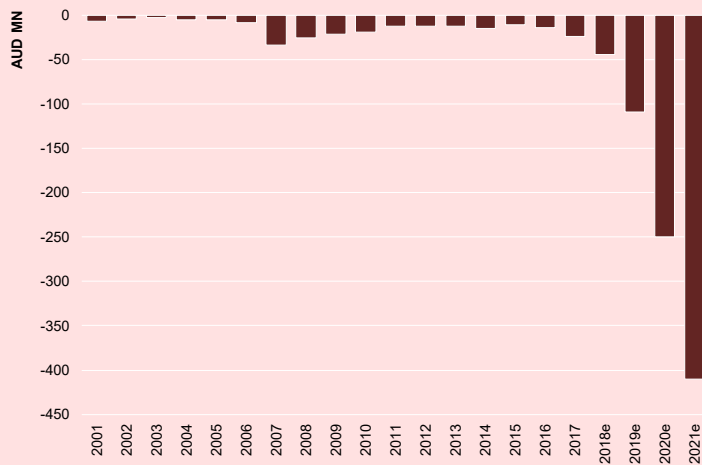
## Business profile (cont.)

### EQUITY AND EQUITY RATIO



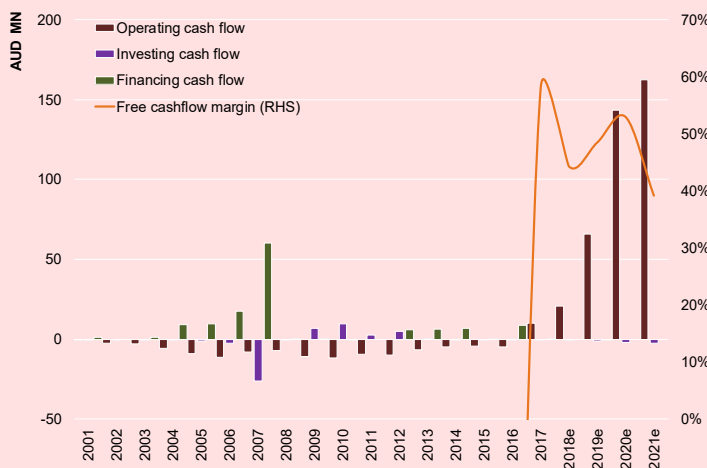
Due to substantial losses, several capital increases were necessary in the past. These measures have kept the equity ratio of the company, which is debt-free from a gross perspective, consistently north of the 80% mark. At the end of the last fiscal year, the equity ratio stood at 88.9%.

### NET DEBT



Clinuvel has been a debt free company since its IPO. Since we expect no dividend payment for the near future, net cash should raise to AUD 410.1 mn by the end of our planning horizon in 2020/21e.

### CASH FLOW



We expect Clinuvel to continue its path of positive free cash flow that started last fiscal year. Overall, free cash flows should add up to AUD 386.5 mn for the full period 2017/18e-20/21e. FCF margin should increase during this period to up to 39.1%.

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Company valuation (EPP case)

Presuming a huge and untapped market potential, in which Clinuvel has a patent protected monopolistic position, our valuation methodology is a standardized three-stage discounted cash flow (DCF) entity model which, as of our view, best reflects the long-term growth opportunities of the company. In our model, we calculate a base-case scenario equity value of AUD 1,490.8 mn or AUD 31.70 per share; a Monte Carlo simulation calculates bear and bull case scenario equity values of AUD 25.90 and AUD 43.00 per share, respectively.

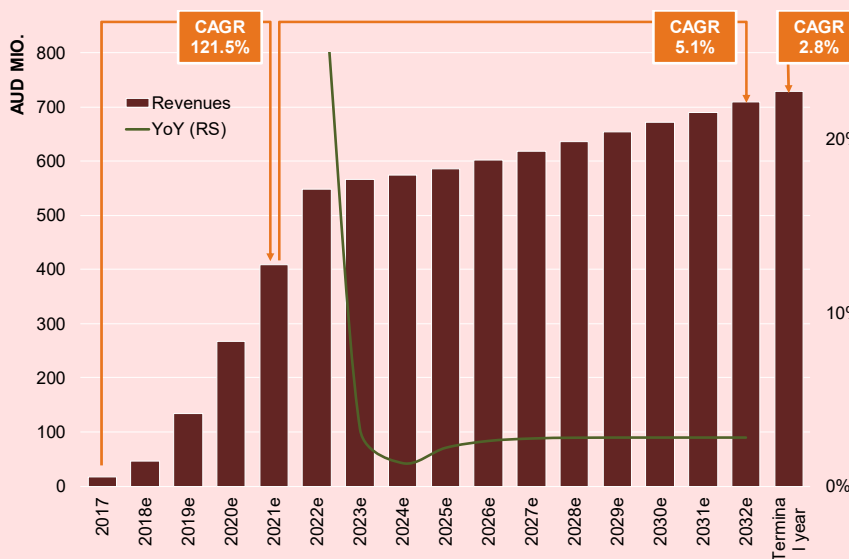
Our equity valuation is based on the treatment of EPP only. Neither vitiligo nor topical products or any of the promising neurodegenerative products have been taken into account due to a lack of transparency about their potential impact. We therefore consider our valuation a worst-case model.

### Valuation methodology overview

Our valuation method for Clinuvel is a three-phase and fully integrated discounted cash flow (DCF) model. As typical for the industry, Clinuvel' business model is characterized by relatively low capital intensity: Capital requirements for investments in tangible fixed assets have been limited in the last few years, and working capital is negligible, too. The funding of further growth will thus not require high net capital expenditures, according to our estimates. Therefore, a high cash conversion rate can, in principle, be deduced from Clinuvel' business model, since the company turned profitable last year. In conjunction with our growth-scenario assumptions, a standardized three-phase DCF model with a long-term orientation is therefore the most suitable valuation approach for Clinuvel.

A long-term DCF model should best reflect the rewards of a patent protected market.

EXHIBIT 1: REVENUES AND REVENUE GROWTH



We expect a continuation of the most recent strong growth trend in the years 2017/18e-20/21e and forecast an increase in revenues to AUD 409.1 mn (2020/21e). After 2020/21e, we model the so called "rough planning phase" of our three-stage discounted cashflow model, which ends in 2031/32e. During this period, we have modelled an average annual revenue growth rate of 5.1% (CAGR 2020/21e-31/32e). Our growth forecast in the terminal value is 2.8%, which is equivalent with the quasi risk-free interest rates in Australia (represented by 10-year sovereign bonds).

SOURCE: SPHENE CAPITAL FORECASTS

### Basic assumptions of the DCF model

In our standardized three-stage DCF model, we have used detailed income-statement and balance-sheet projections for Clinuvel for the first phase through 2020/21e. During this period, revenues are expected to grow by an annual average rate of 121.5% (CAGR 2016/17-20/21e). This high growth period is followed by a second "rough-planning phase" ending in 2031/32e, for which we have assumed average annual growth rates of 5.1%. Our growth forecast in the terminal value is 2.8%, which is equivalent with the quasi risk-free interest rates, represented by 10-year Australian sovereign bonds.

The model is based on our detailed income-statement and balance-sheet projections for the period through 2020/21e. This is followed by a second rough-planning phase ending in 2031/32e.

## Our DCF model is based on the following assumptions:

- Ⓢ **Pre-tax operating margins:** In the years of the rough planning phase after-tax operating margins should decrease gradually from 56.8% in 2019/20e (peak margins) to 35.5% in the last year of our rough planning phase;
- Ⓢ For the **terminal value phase**, we have assumed pre-tax operating margins of 35.0% which is the current average pre-tax operating margin of global pharmaceutical drug manufacturers;
- Ⓢ Marginal **tax rates** are expected to be 30.7% over the whole forecast period after tax loss carry forwards will be exploited in 2019/20e;
- Ⓢ Average **free cash flow (FCF) growth rate** during the terminal phase is expected to be 2.8%, which corresponds to the quasi risk-free interest rate of 10-year Australian sovereign bonds, which represent an appropriate benchmark for risk-free growth in our view;
- Ⓢ We calculate a **fundamental beta** of 1.4, which is derived from the following assumptions:

Overview of our assumptions

### EXHIBIT 2: DERIVATION OF FUNDAMENTAL BETA, 2017/18E-2020/21E

Degree of diversification	0.10
Competitive intensity	0.00
Business model maturity	0.00
Regulatory risks	0.10
Financial risks	0.10
Earnings forecast risks	0.10
Liquidity premium for pre-IPO valuation	0.00
Market beta	1.00
<b>Fundamental beta</b>	<b>1.40</b>

SOURCE: SPHENE CAPITAL

- Ⓢ Being a debt free company, only rough assumptions about the likely risk premium for financial debt can be made. We expect a corporate credit rating of B+. To be on the conservative side, we expect debt risk premiums of about 6.0% in current depressed credit markets;
- Ⓢ Applying a recovery rate of 50%, we calculate an average annual **probability of default** of currently 9.0% for the terminal value (which we consider a very conservative approach);
- Ⓢ We expect a steadily declining asset turnover, enabling Clinuvel to generate revenue growth with lower capex needs in the future;
- Ⓢ Current **weighted average cost of capital (WACC)** are composed of the risk-free interest rate of currently 2.8%, determined from the yield on long-term (10-year) Australian government bonds and an implicit risk premium for the overall market of currently 8.0% (geometric mean). Finally, we assume that Clinuvel is targeting equity and debt capital structure of ~85%/15% representing the current debt to capital ratios of global pharmaceutical drug manufacturers. In total the weighted average costs of capital in the beginning of our detailed planning phase (2017/18e-19/20e) are expected to be approximately 14.1%.
- Ⓢ In our model, Clinuvel will have **WACC in the terminal value**, which do not differ from those of other mature companies. Accordingly, we assume a decrease of WACC from 14.1% to 7.8% in the terminal stage, representing an equity risk premium of 500 bps.

**EXHIBIT 3: WACC IN THE ROUGH PLANNING PHASE, 2017/18E-19/20E**

<b>Cost of Equity</b>	%	<b>14.0%</b>
Risk free rate 30-year Bund	%	2.8%
beta		1.40
Risk premium	%	8.0%
<b>Small caps premium</b>	%	<b>1.0%</b>
Management premium	%	1.0%
Liquidity premium	%	0.0%
Private company premium	%	0.0%
Target equity structure	%	85.0%
<b>Weighted costs of equity</b>	%	<b>12.8%</b>
<b>Cost of debt</b>	%	<b>8.8%</b>
Risk free rate 10-year Australian government bond	%	2.8%
Risk premium liabilities	%	6.0%
Tax rate	%	0.0%
Cost of debt after tax	%	15.0%
<b>Weighted costs of debt</b>	%	<b>1.3%</b>
<b>WACC based on target values</b>	%	<b>14.1%</b>

SOURCE: SPHENE CAPITAL FORECASTS

**Our base-case scenario indicates an equity value of AUD 31.70 per share**

We calculate an enterprise value of AUD 1,490.8 mn. In these computations, 21.5% of our enterprise value calculation is derived from the terminal value, 18.3% from cash flows generated in the detailed planning phase 2017/18e-20/21e and 60.2% from cash flows generated in the subsequent rough planning phase 2021/22e-31/32e.

Equity value of Clinuvel (base case scenario) is AUD 31.70 per share

**EXHIBIT 4: DCF MODEL SUMMARY**

Terminal cashflow	AUD mn	248.5
Terminal cost of capital	%	7.8%
Terminal value	AUD mn	1,615.5
PV (Terminal value)	AUD mn	320.7
Share in EV	%	21.5%
PV (CF 2017/18e-20/21e)	AUD mn	272.3
Share in EV	%	18.3%
PV (CF 2021/22e-31/32e)	AUD mn	897.8
Share in EV	%	60.2%
<b>Enterprise value</b>	<b>AUD mn</b>	<b>1,490.8</b>
Financial debt	AUD mn	0.0
Excess cash	AUD mn	23.8
Value of equity	AUD mn	<b>1,514.5</b>
Number of shares	mn	47.7
<b>Value per share</b>	<b>AUD</b>	<b>31.70</b>

SOURCE: SPHENE CAPITAL FORECASTS

**Valuation at price target**

Vis a vis the current share price of AUD 8.65, our intrinsic company value represents an upside of 266.5%. We therefore initiate research coverage of Clinuvel with a buy rating.

On the basis of our financial forecasts and upon realization of the value of equity we have calculated (base-case scenario), the Clinuvel stock would feature the



following valuation multiples:

### EXHIBIT 5: VALUATION MULTIPLES – CURRENT VS. PRICE TARGET

X	Valuation at current price		Valuation at price target of AUD 31.70	
	2018/19e	2019/20e	2018/19e	2019/20e
P/E	4.6x	2.2x	5.7x	2.7x
EV/Sales	1.7x	0.3x	2.3x	0.6x
EV/EBIT	3.1x	0.5x	4.2x	1.1x
P/BV	2.8x	1.2x	3.4x	1.5x

SOURCE: SPHENE CAPITAL FORECASTS

### Stock performance catalysts

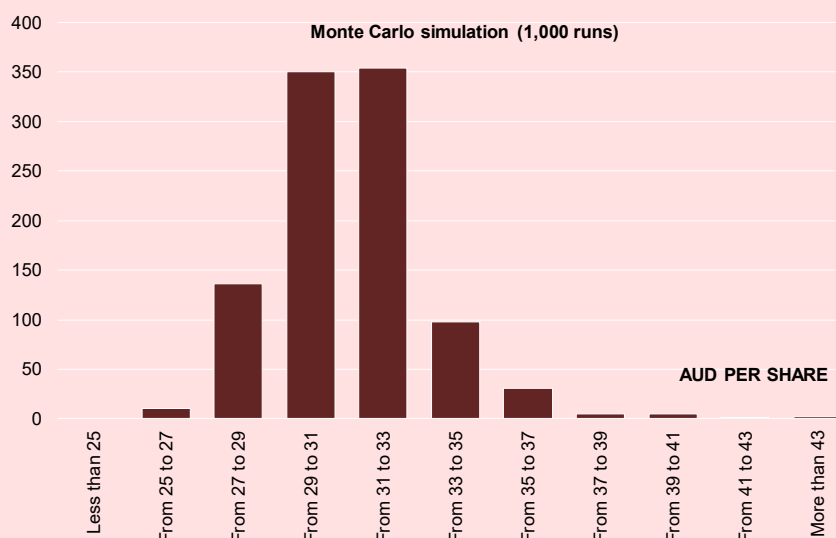
In our view, the most important catalysts for Clinuvel's stock performance in the coming months are: **(1)** statements on the current status of FDA approval, **(2)** statements on the status of the clinical trials for the vitiligo product, **(3)** a further year-on-year earnings improvement in 2017/18e; **(4)** statements on the company's willingness to interact with its shareholders.

Catalysts for realization of the computed price target

### Monte Carlo simulation

In a Monte Carlo simulation, potential values for rough planning phase growth rates and during the terminal value were given through random variables. In total, we tested and evaluated 1,000 combinations of the two variables, with the outcome, that equity values of less than AUD 25.90 and more than AUD 43.00 per share could not be achieved by combinations of the two variables. (see exhibit 6 below).

### EXHIBIT 6: MONTE CARLO SIMULATION



The scenario analysis is based on the assumptions underlying the model, with deviations in the average annual growth rate during the rough planning phase and the terminal value. The result is a left-angled (right-hand) distribution with a mode for values of equity between AUD 31 and 33 per share.

SOURCE: SPHENE CAPITAL FORECASTS

### Weaknesses and threats

We see the following risks for our valuation findings: **(1)** Management considers shareholders are only one among many stakeholders and seems not to be interested in maximizing shareholder's value; **(2)** Approval procedures seem to be more time consuming than usual, since many payors have been unaware of the need to treat EPP patients due to the rarity of the disease; **(3)** Since Clinuvel has restricted the product's availability only to those expert centres who have worked with EPP patients, long-term growth could be endangered by this strategy; **(4)**

Should the FDA reject Scenesse as an EPP treatment in the US, Clinuvel would miss approximately two thirds of its revenue and profit potential, which would imply a substantial downside to our price target; **(5)** Any safety concern about the use of Scenesse to treat EPP could delay extension of the product to other applications, or might in an extreme case lead to a stop of distribution; **(6)** Turning Clinuvel from a research driven company into a commercial global entity entails certain organizational risks, which could endanger the profitability of the company and therefore our price target; **(7)** Growth from vitiligo might not materialize as expected, because injections may not respond properly to the local spots of non-pigmented skin properly; **(8)** Clinuvel could not handle the complexity of organizational growth and could fail to manage the high-resource R&D and study work necessary for all the future applications.

## The light protection enabler

Australia-based Clinuvel Pharmaceuticals (Clinuvel) is a biopharmaceutical company developing the photoprotective pharmaceutical drug afamelanotide, a first-in-class dermatological drug that activates the production of melanin, the skin's natural defence against ultraviolet (UV) light, to protect patients from several sun-related diseases. As of today, Clinuvel focuses on the prophylactic treatment of erythropoietic protoporphyria (EPP). Following a successful launch of the EPP treatment, Clinuvel will focus on introducing a Scenesse variant for children, as well as expanding its activities to the treatment of vitiligo, a pigmentation disorder, to some also known as Michael Jackson disease.

In FY 2016/17 (30/06), Clinuvel reported a total output of AUD 17.0 mn and an EBIT of AUD 7.1 mn. The company has no financial debt.

### Key product Scenesse

Clinuvel's lead compound, afamelanotide, is a proprietary first-in-class photoprotective drug. Distributed under the brand name "Scenesse", afamelanotide is a synthetic analogue of the natural peptide hormone Alpha-Melanocyte Stimulating Hormone, short Alpha-MSH or  $\alpha$ -MSH. Normally,  $\alpha$ -MSH is a naturally occurring hormone which is released by skin cells in response to the stimulation by ultraviolet radiation (UVR) following exposure to sunlight or artificial sources of UV. Despite its very short half-life of only a few seconds in the blood stream,  $\alpha$ -MSH stimulates other skin cells (melanocytes) and activates the production of melanin, a dark brown pigment, which provides skin with colour and protection from UV/light. Therefore, melanin is known for its photoprotective effect.

People with a melanin disorder, however, fail to produce an adequate rate and quality of melanin, which constitutes the photoprotective pigmentation of skin and hence protects against UVA and UVB. For example, most people with fair skin produce a more reddish and UVR-ineffective pigmentation, called pheomelanin, instead of a darker pigmentation, eumelanin, which protects against UVR. Fair-skinned individuals are highly deficient in the UV response of their skin due to a deficiency of a specific receptor of the skin cell, the melanocortin 1 receptor that regulates pigment producing skin cells, melanocytes.

Afamelanotide works by effectively giving a boost to the body's natural defences against UV light. Two amino acids present in  $\alpha$ -MSH have been changed and amplified to produce afamelanotide which in turn activates the production of melanin in the skin. These small changes create a more stable molecule with increased potent biologic effects and a longer half-life of several minutes. Though,  $\alpha$ -MSH has a very short half-life, disappearing in a matter of seconds. Afamelanotide has a slight tweak compared with its natural analogue which gives it a more potent effect and a longer half-life. Therefore, Scenesse can increase melanin content of the skin without exposure of the skin to the damaging effects of UVR. It's a tan that almost happens in the dark. Increased pigmentation of the skin appears after two days and lasts up to two months.

### Treatment with afamelanotide

Since treatment is especially important for individuals with light skin, who are particularly prone to skin disorders, Clinuvel

- ⑤ uses Scenesse as a prophylactic treatment to patients suffering from light and UV related skin disorders (photodermatoses), mainly **erythropoietic protoporphyria (EPP)**, by stimulating the production of melanin to act as a photoprotective filtering the impact of UV to the skin,
- ⑤ and is currently trialling Scenesse as a repigmentation therapy in **vitiligo**, where the drug is being evaluated in combination with narrowband ultraviolet B phototherapy (NB-UVB).

### Additional potential treatment (long-term)

Besides EPP and vitiligo, afamelanotide has also been trialled for its ability to prevent other photosensitivity disorders including

- ⑤ **Squamous cell carcinoma (SCC)**, also known as epidermoid carcinoma, an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers (the epidermis);

Discovered at University of Arizona and initially developed as a sunless tanning agent, Clinuvel conducted further clinical trials and eventually brought the drug afamelanotide to market.

The amino acid sequence of afamelanotide is Ac-Ser-Tyr-Ser-Nle-Glu-His-D-Phe-Arg-Trp-Gly-Lys-Pro-Val-NH<sub>2</sub>, and it is additionally known as [Nle<sup>4</sup>,D-Phe<sup>7</sup>]- $\alpha$ -MSH, which is sometimes abbreviated as NDP-MSH or NDP- $\alpha$ -MSH.

- ⑤ **Actinic keratosis (AK)**, also known as a solar keratosis, is a crusty, scaly growth caused by damage from exposure to ultraviolet (UV) radiation; and
- ⑤ **Solar urticaria (SU)**, a rare form of physical urticaria (hives) in which the skin swells within minutes of exposure to natural sunlight or an artificial light source emitting ultraviolet radiation, resulting in painful itchy welts.

**Erythropoietic protoporphyria (EPP) is an inherited disorder of the haem metabolic pathway characterised by accumulation of protoporphyrin in blood, erythrocytes and tissues, and cutaneous manifestations of photosensitivity (as defined by Lecha et al.; Licensee BioMed Central Ltd., 2009). Patients with EPP experience severe anaphylactoid reactions and burns (phototoxicity) following even brief exposure to visible light, both of artificial and natural light sources, which can incapacitate patients for days or week. EPP is a rare disease that has been reported with a worldwide prevalence between 1:75,000 and 1:200,000. It usually manifests in early infancy upon the first sun exposures. Clinuvel's key product Scenesse activates melanocytic output (pigment cells) of the epidermis and the resulting eumelanin acts as a protective light barrier and potent antioxidant.**

#### **Disease symptoms and consequences of EPP, the “invisible disease”**

Erythropoietic protoporphyria (EPP), also known as Protoporphyria, Haem synthetase deficiency, Ferrochelatase deficiency, X-linked dominant protoporphyria (XLDPP), is classified as so called “rare disease”, which as defined by the European Union affect less than 1 in 2,000 people of the general population. It is a form of cutaneous photosensitivity to visible light usually commencing in early childhood and remaining for life caused by malfunctions during the haem biosynthetic pathway and resulting in an accumulation of a chemical known as protoporphyrin. Protoporphyrin is a molecule toxic to the body that transforms into excited states on absorption of light energy and accumulates in various tissues, mainly within red blood cells and plasma eventually causing photo-oxidative damage to the skin.

#### **The undercover life of EPP patients**

The amount of exposure to sun or even UV light that a patient with EPP can tolerate varies from a few minutes to several hours. The symptoms vary based on the intensity and duration of the sun exposure. After longer exposure EPP-patients report, in decreasing order of frequency, burning, swelling, and itching of the skin. In some cases, affected individuals have exhibited abnormal accumulations of body fluid under affected areas (edema) or persistent redness or inflammation of the skin (erythema). Usually, these symptoms subside in 12 to 24 hours and heal without significant scarring.

After severe episodes of photosensitivity, however, some patients acquire shallow-depressed scars over the nose, cheeks and on the backs of hands as well as grooving around the lips. In extreme cases or after a long time of sickness, protoporphyrin build-up can cause general tissue nerve damage that can result in abdomen pain, stomach reflux and temporary psychosis. Approximately 20 to 30% of the affected individuals suffer from some degree of liver dysfunction, which is typically mild; up to 5% however, may develop more advanced and even life threatening liver disease.

Since the photosensitivity results from light in the visual spectrum (320 to 595 nm) as well as UV, window glass does not offer protection from wavelengths. Even hypersensitivity of the skin to some types of artificial light is common. Typically, impact on a patient's lifestyle, employment, travel, and recreation is dramatic: While EPP patients typically experience the onset of photosensitivity before the age of six years, EPP patients are conditioned from childhood to avoid the risk of second degree burn and anaphylactoid reactions. Typically, EPP patients spend a considerable amount of time avoiding all sources of light. They wear clothes protecting the whole body, tend to live in darkness and may become socially isolated. A study carried out in the UK (Holme et al. in Br. J. Dermatol., 2006) to assess quality of life in a large sample of EPP patients revealed that EPP ranks among of the most disabling of skin conditions, despite a relative paucity of visible signs.

#### **Stigmatization of EPP patients**

Notwithstanding these effects, many EPP patients report that they have not been

EPP is one of a group of disorders known as the porphyrias. Porphyrias are characterized by abnormally high levels of particular chemicals (porphyrins) in the body due to deficiencies of certain enzymes essential to the synthesis of haemoglobin.

The symptoms associated with the various types of porphyria differ, depending upon the specific enzyme that is deficient. The word 'erythropoietic' means associated with red blood cells ('erythro-') and their formation ('-poietic'). Therefore, the major symptom of EPP is hypersensitivity of the skin to sunlight and some types of artificial light, such as fluorescent lights (photosensitivity).

Pain might be severe and not alleviated by narcotic analgesics and can persist for hours or even days after the initial phototoxic reaction

taken seriously by society, by those within their immediate environment, and by their general physicians. Therefore, suicide rates are high among medically neglected EPP patients.

## EXHIBIT 7: CHRONIC SKIN LESIONS OF EPP PATIENTS FOLLOWING SUN EXPOSURE



SOURCE: ORPHANET JOURNAL OF RARE DISEASES (2009), VOL. 4:19, COMPANY DATA

### Causes of EPP

With only rare exceptions, EPP is a hereditary disease inherited as an autosomal dominant genetic trait with poor penetrance. Human traits, including the classic genetic diseases, are the product of the interaction of two genes, one received from the father and one from the mother in dominant disorders, a single copy of the disease gene (received from either the mother or father) will be expressed "dominating" the other normal gene and resulting in the appearance of the disease.

### Market size of EPP (prevalence)

EPP is a very rare inherited disorder that affects males and females in equal numbers. The onset of symptoms affecting the skin usually occurs in infancy; however, in some cases, onset may not occur until adolescence or adulthood.

More than 300 cases of EPP have been reported in the medical literature.

With a global prevalence to be estimated somewhere between 1:75,000 and 1:200,000, an estimated 40,000-100,000 people suffer from EPP worldwide. Statistically, we estimate there are between 7,000 and 14,000 EPP sufferers in the US and Europe (i. e. Clinuvel's prime markets), though accurate data are hard to find. During the past years, however, the prevalence of EPP has substantially increased due to a better understanding of the disease and improved diagnosis.

### Traditional treatments of EPP

The genetic defect as the cause of EPP cannot be treated causally. Topical sunscreens, which are effective in protecting against hypersensitivity to the sunburn spectrum of light, as well as various systemic agents, such as antimalarials, inosine and vitamin E, have been tried but with little success. The most widespread treatment of EPP is complete sun avoidance by remaining indoors and wearing sunglasses and sun protective clothing garments with long sleeves and long trousers including gloves and broad-brimmed hats. Individuals with EPP may also benefit from window tinting or using vinyls or films to cover the windows in their car or house.

To prevent discomfort, people affected so far could only avoid sunlight and forgo an excessive stay outdoors.

Symptomatic treatment is limited to symptomatic relief, for example by immersing affected skin into water. Beta-carotene, a natural product found in green plants, can be used as a protective measure to lessen symptoms of photosensitivity too, but cannot be considered a treatment due to a lack of effectiveness.

### Clinuvel's treatment

With no real treatment options for EPP sufferers beyond limiting light exposure, Clinuvel's afamelanotide medicine called "Scenesse" is the only viable treatment option for EPP.

With afamelanotide the skin pigmentation increases and thus offers a certain sun protection.

Scenesse is a chemical analogue of  $\alpha$ -MSH. Two amino acids present in  $\alpha$ -MSH have been modified and amplified to produce afamelanotide. This small change creates a more stable molecule with increased potent biologic effects and a longer

half-life (minutes). Eventually, Scenesse increases the melanin content of the skin without exposure of the skin to the damaging effects of UVR. When exposed to sunlight, increased pigmentation of the skin appears after two days and lasts up to two months.

#### **Delivery through subcutaneous dissolving implants**

Scenesse is delivered via a subcutaneous dissolving implant in the iliac crest of the hip, approximately the size of a grain of rice. Patients need to be periodically treated for their entire life.

#### **Impressive clinical results**

For subcutaneous implants containing the active ingredient afamelanotide, EPP has so far been the subject of two placebo-controlled phase III studies (Europe and the USA). The aim of the studies was to determine how long patients with EPP can stay in the sun without symptoms. The results of the studies were impressive: The individual daily pain scores were not only significantly lower in patients receiving Scenesse compared to those receiving the placebo, patients receiving afamelanotide managed to stay for an average of 115.6 hours in the sun, whereas the placebo group only lasted for 60.6 hours.

Reports from clinical studies over the last decade have indicated that EPP patients treated with Scenesse

- ⑤ lose their anxiety for burns and anaphylactoid reactions;
- ⑤ gradually expose their skin to light sources; and
- ⑤ participate in daily activities – which had been impossible prior to treatment.

According to the company, more than 900 patients have been treated with Scenesse in more than 20 clinical trials and several indications. While Scenesse has been shown to reduce the incidence and severity of phototoxic reactions, results suggest that the drug is well tolerated. Further studies of Scenesse are underway as a repigmentary agent in vitiligo.

#### **Overcoming further drawbacks**

The main problem arose in that scientific studies for proof of action of new drugs are performed double-blinded. Normally, in double-blinded tests neither the patients nor the controlling medical staff should know whether the patient has been treated with the effective preparation or with a placebo. The patients who were treated with Scenesse, however, very soon found out that they were treated with Scenesse. Their skin turned darker, since Scenesse promotes the formation of the body's own skin pigment melanin. This made the evaluating authorities to question the studies, because the objectivity of the study was not given. Only the involvement of various EPP organizations has ultimately helped to convince the authorities of the tremendous gain in quality of life.

#### **Internationalization strategy**

In 2014, Clinuvel has obtained EMA (European Medicines Agency) authorisation under exceptional circumstances for the marketing of its photoprotective drug Scenesse, for the prevention of phototoxicity in adults with the orphan disease EPP. The marketing authorisation was granted due to the unique nature of EPP and the lack of scientific tools available to quantify the disease or a treatment. Since approval Clinuvel has established a compliant pharmacovigilance system to monitor drug safety, and the first ever international EPP disease registry to collect long term safety and effectiveness outcomes endpoints. Pseudonymised data are collected from patients receiving the drug at European EPP Expert Centres.

A gradual roll-out per country is being pursued, after the authorization has been granted by the European Commission. Discussions with each National Competent Authority and payment institution are held to ensure market access for Scenesse:

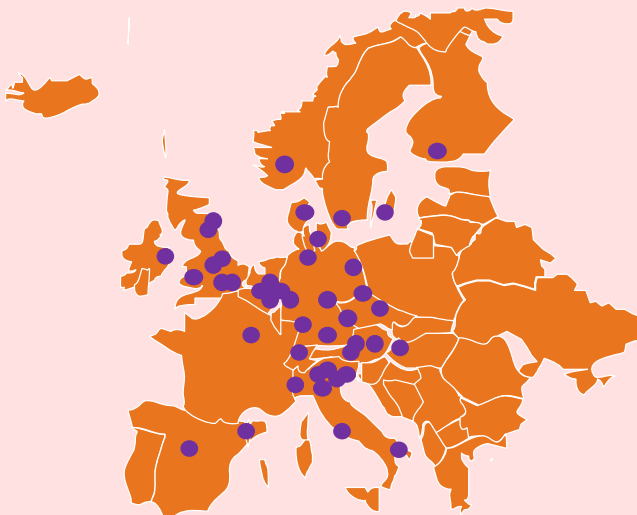
- ⑤ In **Germany**, Clinuvel reached pricing agreement with the German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband or GKV-SV) for the EPP treatment with Scenesse, which is legally binding for all state insurers in Germany.
- ⑤ In the **Netherlands**, Scenesse has been reimbursed since 2016.
- ⑤ In **England**, Scenesse is not currently reimbursed for EPP, notwithstanding that it has been adopted as standard of care for adult EPP patients in

surrounding European reference countries. In December 2017, the National Institute of Health and Care Excellence (NICE), which acts as the advisory body to the English National Health Service (NHS), published a draft not to recommend reimbursement for Scenesse by the NHS in England. A final recommendation for reimbursement to NHS England is expected in May 2018.

- S In the **US**, Scenesse was granted orphan drug designation by the FDA in 2008 for the treatment of EPP patients and Fast Track Designation (FTD) in 2016, allowing for a “rolling review” of the NDA. The orphan drug designation provides R&D and review incentives for drugs which may not otherwise be commercially viable to develop, while FTD assists to ensure that innovative drugs reach the patient population earlier than would be the case during a standard review process. The rolling review under the FTD allows the FDA to start the review of the scientific dossier only when all modules have been submitted and have passed formal validation, a two-month process after submission of the final NDA module. We expect the final NDA submission during the first half of 2018.

In Europe, Scenesse will be distributed to specialised centres as a hospital-only prescription product. As of today, there are 42 EPP centres in Europe.

## EXHIBIT 8: EPP EXPERT CENTRES IN EUROPE



SOURCE: COMPANY DATA

In each country there is typically one National Reference Centre for porphyria or rare metabolic disorders, supported by satellite centres. EPP is typically treated in university hospitals, where various medical specialties look after the patients.

As of today, there are 42 European EPP “Expert Centres” who have indicated a willingness to prescribe Scenesse for their patients.

### Clinuvel’s pricing between EUR 56,404 and EUR 84,606 per patient p.a.

In April 2017, Clinuvel announced that it had reached an agreement with the German government reimbursement body, the German Association of National Health Insurance Funds (“GKV-Spitzenverband”), for the treatment of EPP patients with Scenesse. In Germany, the disease affects between 500 and 1,090 patients (based on disease prevalence). The annual costs of Scenesse therapy depends on number of implant injections per annum and range between EUR 56,004 and EUR 84,606 per EPP patient according to company data. Therefore, we estimate total market for EPP treatment in Germany to be between EUR 28.0 mn and EUR 91.6 mn per year.

Since Clinuvel has adopted a uniform global pricing policy, we expect similar pricing will be negotiated in other countries. As of today, Clinuvel’s sales scientists are engaging with the European payment agencies one by one to introduce Scenesse to each individual European country.

**Vitiligo is a skin disorder affecting 1-4% of the world population, independently of ethnicity. The disease is characterized by milky white patches due to a loss of functional melanocytes from the epidermis. Vitiligo patients feel distressed and stigmatized by their condition. Several theories have been proposed to explain the etiopathogenesis of vitiligo, but none of the hypotheses explains the entire spectrum of this disorder.**

#### Disease symptoms and consequences

Vitiligo, to some also known as Michael Jackson-disease, is a chronic pigmentation disorder. The disease is characterized by chalk or milk white spots, which tend to occur on the extremities of the hand, the face, and the feet, but also on both the mucous membranes (tissues that line the inside of the mouth and nose), and the retina (inner layer of the eyeball). These patches of the skin (and also the hair from the skin) gradually lose their pigments. Initially, spots are small, but often grow and change shape and eventually become white with sharp margins.

Patches are usually well demarcated and enlarge centrifugally in size by time.

Vitiligo is classified into three main types, based on the distribution of the lesions:

- ⑤ **Bilateral, non-segmental type** (~85-90% of all cases) of vitiligo: this type of vitiligo (usually termed “generalized” vitiligo) produces depigmentation that is symmetrical in distribution; bilateral vitiligo can begin at any age and tends to progress intermittently over the life of the patient, affecting both sides (hence “bilateral”) of the body.
- ⑤ **Unilateral (segmental) type** (~10-15% of all cases) of vitiligo: this “localized” type of vitiligo more commonly begins in childhood or adolescence and progresses for a limited period, usually 1–2 years, and then remains static for the life of the individual. Segmental vitiligo affects only one segment of the body, such as a leg, face, or arm.
- ⑤ **Universal type** (very rare) of vitiligo: this is a near complete loss of pigment of more than 80% of the body.

#### EXHIBIT 9: NON-SEGMENTAL VITILIGO (LEFT) AND SEGMENTAL VITILIGO (RIGHT)



SOURCE: AMERICAN ACADEMY OF DERMATOLOGY

#### Causes of vitiligo

The white spots are created when the transportation of melanin from the basal layer of the epidermis to the upper levels is inhibited or retarded. Eventually, an excessive immune reaction induces melanocytes (the cells that make pigment) to undergo natural cell death, and depigmentation of the skin results.

Although multiple hypotheses have been suggested as potential triggers that cause vitiligo, studies strongly imply that changes in the immune system should be responsible for that condition. Vitiligo has been proposed to be a multifactorial disease with three known reasons thought to play an important role for the transportation of melanin to be impeded:

- ⑤ **Genetic reasons:** There are three genes identified, vitiligo patients have in



common which predisposes them to destruction of melanocytes;

- ⑤ **Autoimmune reasons:** Vitiligo has been linked to several other autoimmune diseases such as diabetes mellitus, Addison's disease, pernicious anaemia, rheumatoid arthritis, psoriasis and Grave's disease. Vitiligo patients have been discovered as having an increased number of lymphocytes, which are reactive to the antigens (molecule on the surface of a cell) on melanocytes. These lymphocytes detect and eventually destroy melanocytes.
- ⑤ **Environmental reasons:** Certain environmental conditions like illness, emotional stress, severe sunburn, and pregnancy have all been implicated as possible aggravating factors.

### Market size of vitiligo (prevalence)

Vitiligo globally affects approximately 1-4% of the world population (i. e. between 75 and 300 mn individuals). Approximately half of them develop vitiligo under the age of 20; most people develop the disease before their 40th birthday. Male and female of all races are equally affected by the disorder; however, it is more noticeable in people with darker skin. Vitiligo may also be hereditary, in that 30% of people with vitiligo have a family member with the disease.

Prevalence of vitiligo is substantially larger than EPP.

### Traditional treatments of vitiligo

Many patients believe that having two colours on visible skin such as hands, face, neck, and arms is an unbearable condition for them to have. Therefore, these patients regularly choose a depigmentation of the unaffected skin by applications of monobenzone, in order to achieve a single colour on the whole body.

Several medical therapies, most of which are applied topically, can reduce the appearance of white patches with vitiligo. The most commonly medical therapies are:

- ⑤ **Topical steroid therapy:** Corticosteroid creams may be helpful in repigmenting white patches, particularly if they are applied in the initial stage of the disease. They act by suppressing the immune system to prevent the destruction of melanocytes, slowing the progression of vitiligo and allowing for repigmentation. Corticosteroids are most effective on small areas of the face and repigmentation by this method is more successful in dark-skinned individuals. Potential side effects include skin shrinkage and skin striae (streaks or lines on the skin), telangiectasias (dilated blood vessels) and hypertrichosis (abnormal hair growth).
- ⑤ **Depigmentation:** wherein case of extensive vitiligo (more than 80% of the body), some patients opt to undergo depigmentation which involves fading the rest of the skin on the body to match the areas that are already white. This treatment involves the use of topical monobenzyl ether of hydroquinone (Benoquin). The major side effect of depigmentation therapy is inflammation (redness and swelling) of the skin.
- ⑤ **Immunomodulators:** Certain creams containing agents such as tacrolimus and pimecrolimus can be used to reduce the immune response against melanocytes.
- ⑤ **Calcium modulators:** Research shows that calcium transport in the melanocytes of vitiligo patients is often defective. Since vitamin D3 aids in calcium transport, it's analogues (calcipotriol and tacalcitol) have been trialled as a vitiligo treatment with varying success.

Surgical therapies are considered only after other therapies have proven ineffective since they are usually expensive and can leave scarring:

- ⑤ **Autologous skin grafting:** Autologous (also called autogenous, autogeneic, or autogenic tissue) skin grafting is primarily used for patients with small patches of vitiligo. During the treatment, the doctor removes sections of the normal, pigmented skin (donor sites) and places them on the depigmented areas (recipient sites). Alternatively, the doctor creates blisters on pigmented skin by using heat, suction, or freezing cold; afterwards, the tops of the blisters are cut out and transplanted to recipient sites.
- ⑤ **Micro-pigmentation (tattooing):** This procedure involves implanting pigment into the skin with special surgical instruments.

- ⑤ **Autologous melanocyte transplantation:** After the doctor took a sample of normal pigmented skin, he places it in a laboratory dish containing a cell-culture solution to grow melanocytes. When the melanocytes in the culture solution have multiplied, the doctor transplants them to depigmented skin patches. This procedure is currently experimental.

Ultraviolet (UV) radiation can be used as a therapy to restore pigment to the skin:

- ⑤ **Narrow band UVB (NB-UVB) phototherapy:** NB-UVB phototherapy therapy has emerged as the gold standard of repigmentation treatment in individuals affected by vitiligo. When vitiligo skin is exposed to an intensive dose of UVB radiation, melanin is activated in lesions of the skin and new melanocytes producing the melanin from the hair follicle bulge migrate to the skin surrounding the hair follicle. Eventually, small spots of repigmentation will form within the lesion. As the melanocytes continue to migrate and produce melanin, these “islands” begin to spread and merge, eventually creating a repigmentation in the treated area. This therapy is known to effectively suppress the local immune response and accelerate the maturity of melanocytes in the area around hair follicles, which act as melanocyte reservoirs. Clinuvel uses Scenesse (Afamelanotide 16mg) as an adjunct to treatment with NB-UVB, as well as testing afamelanotide as a single treatment option. Both UVA and NB-UVB are potent melanocyte stimulants for repigmentation.
- ⑤ **Psoralen ultraviolet photo-chemotherapy PUVA therapy:** Taken orally or applying it to the skin, psoralen is a drug that contains chemicals that react with ultraviolet A (UVA) light to cause darkening of the skin. Major side effects of topical PUVA therapy are (1) severe sunburn and blistering and (2) too much repigmentation (hyperpigmentation) or darkening of the treated patches or the normal skin surrounding the vitiligo. Oral psoralen photochemotherapy may also increase the risk of skin cancer.
- ⑤ **Sunlight overexposure with the full UV spectrum:** Depending on the intensity of UV light exposure, sunlight overexposure may induce marked pigmentation with diffuse skin darkening.

**Clinuvel's treatment**

The patent for use of afamelanotide in vitiligo was granted 2017.

NB-UVB provides an indication that melanocytes are present in vitiliginous lesions of patients. Where melanocytes are present, their melanocortin-1 receptors are available. This in turn means that there is an opportunity for Scenesse to activate the melanocytes. The belief is widely supported that when administered in the right fashion, Scenesse will act as a chemical agent to the melanocytes in combination with and after providing the physical stimulant for narrowband UVB photo therapy.

**EXHIBIT 10: REPIGMENTATION FOLLOWING TREATMENT WITH VITILIGO**



From top left to bottom right:  
**Baseline**  
**Day 35** after 15 NB-UVB sessions and 1 Scenesse implant;  
**Day 66** after 29 NB-UVB sessions and 2 implants;  
**Day 171** after 62 NB-UVB sessions and 4 implants.

SOURCE: COMPANY DATA

Results in the use of Scenesse in clinical trials have shown that monthly doses of Scenesse for 4 to 6 months in combination with twice or thrice weekly administered NB-UVB light provides optimum repigmentation in patients with

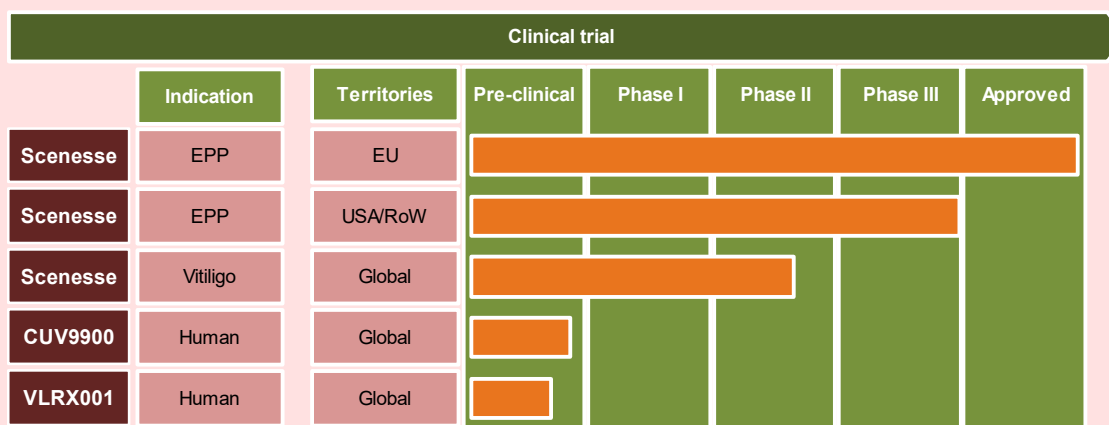
darker skin complexion. While EPP needs to be treated lifelong, Scenesse will be a curative or definitive treatment with vitiligo patients. After an estimated 6 to 10 injections (depending on the severity and extent of depigmentation), vitiligo will be cured according to company information.

### Internationalization strategy

Only if the US FDA approves the use of Scenesse in EPP, Clinuvel has stated to expand resources on a larger vitiligo population, who would benefit from a repigmentation therapy.

**α-MSH seems to have a wider array of applications which gives Clinuvel the opportunity of pipeline products in the melanogenic domain. Quite untypical for the pharmaceutical industry, Clinuvel’s management does not aggressively comment on their R&D activities, especially regarding demyelinating diseases, where the addressable market is substantially larger than with EPP or vitiligo.**

**EXHIBIT 11: PIPELINE**



SOURCE: COMPANY DATA, SPHENE CAPITAL

### More products in the pipeline

Apart from treatment of EPP and vitiligo, Scenesse may also have a photoprotective effect for patients with other rare forms of cutaneous porphyria: variegate porphyria (VP), hereditary coproporphyria (HCP) and congenital erythropoietic porphyria (CEP). Each of these cutaneous porphyrias has clinically distinct symptoms, generally characterised as acute dermal reactions. While no further trials are currently planned in cutaneous porphyrias, Clinuvel has made Scenesse available to several patients with CEP on a name-patient basis due to the extreme severity and progressive character of this disorder.

Following the approval of Scenesse, Clinuvel is pursuing an expanded pipeline of products from the melanocortin family, both as topical and second generation melanocortin products. Two novel molecules have been announced:

- ⑤ **CUV9900** is an alpha-Melanocyte Stimulating Hormone (α-MSH) analogue, and a novel melanocortin peptide for topical application for skin care. After successful commencement of formulation work, Clinuvel expects the first formulations to be available for clinical testing after the commercialisation of Scenesse in Europe.
- ⑤ **VLRX001** is an addition to the family of melanocortin analogues which provoke increased and prolonged cellular activity. It contains a specific peptide sequence, designed to make it less susceptible to degradation than physiologic (natural) alpha-melanocyte stimulating hormone (α-MSH). Formulation work will focus on the development of VLRX001 for topical self-administration by patients.

Both products will be developed by Clinuvel’s majority owned subsidiary, Vallaurix, an experimental laboratory in Singapore. With 18%, Biotech Lab Singapore (BLS)

is the minority shareholder of Vallaurix. The joint venture with the private company was established in 2014, but no further information was provided since then.

#### **Scenesse for paediatric EPP patients**

Following the request by the regulatory authorities, the teams are also working on the development of “Scenesse Enfance” for children diagnosed with EPP.

#### **With treatment of demyelinating diseases, however, addressable market could get substantially bigger**

In 2016, researchers at the University of Münster investigated possible effects and applications outside of pigment excitation to better understand the mode of action in demyelinating disorders by explicitly using afamelanotide. A demyelinating disease is any disease of the nervous system in which the myelin sheath of neurons is damaged. This damage impairs the conduction of signals in the affected nerves. In turn, the reduction in conduction ability causes deficiency in sensation, movement, cognition, or other functions depending on which nerves are involved.

The results of the study showed long-lasting neuroprotective and anti-inflammatory properties of  $\alpha$ -MSH in the central nervous system of mice. It was demonstrated, that inflammatory reactions to multiple sclerosis (MS) had been significantly reduced by using afamelanotide. Even a complete decline in MS in the mouse model was shown. In addition, side effects seem minor, since afamelanotide is well tolerated.

Afamelanotide blockades inflammatory immune cells in the bloodstream. Due to its neuroprotective effect, afamelanotide also counteracts the degeneration of nerve cells which can be monitored in Alzheimer's disease.

Clinical studies in humans are still pending. However, the pre-clinical studies in the mouse model provide a good basis for a clinical phase 1 study and encourage to further investigate the potential of afamelanotide in humans for neurodegenerative diseases, in our view.

#### **Clinuvel filed a patent in October 2017**

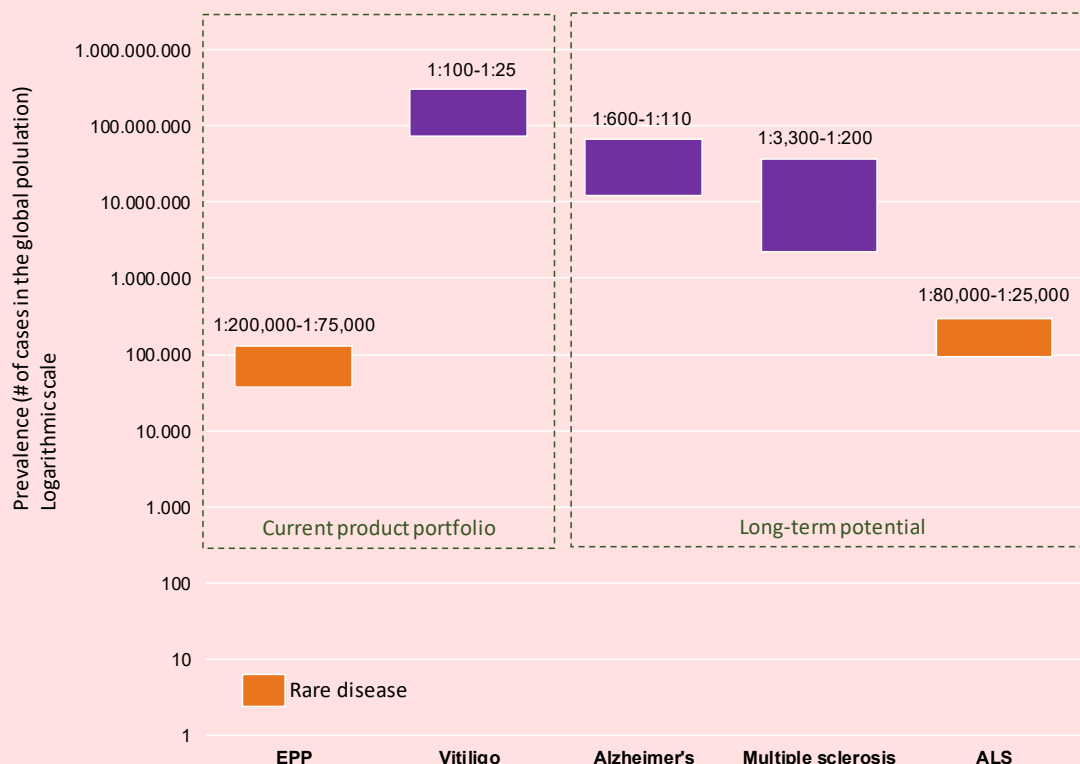
In October 2017, Clinuvel filed a patent for the use of afamelanotide as a treatment of various Central Nervous System (CNS) disorders such as Multiple Sclerosis, dementia, Alzheimer's Disease, Parkinson's Disease, Amyotrophic Lateral Sclerosis (ALS), or Huntington's Disease. The patent mentions “surprising benefits of the particular use of  $\alpha$ -MSH analogues in treatment and/or prevention of Central Nervous System (CNS) disorders”.

#### **Market size of demyelinating disorders**

With increasing life expectancy and the associated general demographic development of the world's population, the numbers in neurodegenerative or demyelinating diseases are on the rise. They include

- ⑤ **Alzheimer's disease** (or short Alzheimer's), a chronic neurodegenerative disease, which most common early symptoms are difficulties in remembering recent events. As the disease advances, additional symptoms include language problems and disorientation; later on, more and more bodily functions are lost, ultimately leading to death.
- ⑤ **Multiple sclerosis** (MS) which is characterized by recurrent inflammatory reactions (“lesions”) that damage the insulating covers of nerve cells in the brain and spinal cord. These damages disrupt the ability of parts of the nervous system to communicate, resulting in physical, mental, and sometimes psychiatric problems.
- ⑤ **Amyotrophic Lateral Sclerosis** (ALS), also known as Lou Gehrig's disease, is a specific disease that causes the death of neurons which control voluntary muscles; ALS is characterized by stiff muscles, muscle twitching, and gradually worsening weakness due to muscles decreasing in size. This results in difficulty speaking, swallowing, and eventually breathing.

**EXHIBIT 12: WORLDWIDE PREVALENCE OF DISEASES WITH POTENTIAL AFAMELANOTIDE TREATMENT**



SOURCE: COMPANY DATA, SPHENE CAPITAL

### Finally, Clinuvel could enter the cosmetics market

In 2017, Clinuvel registered a trademark called “Chivere” in Europe and the US. The trademark is registered for goods and services in the cosmetics and skin care market, with references to sun protection and tanning. This could be the first step to prepare a market entry into a global mass market without regulatory entry barriers. Revenues for the self-tanning product manufacturing industry are expected to be more than USD 1 bn in 2017. Since these applications are topically applied (i. e. without injection), they should face better customer acceptance and allow wider spread use without supervision by medical personnel.

In connection with the topical skin care market, Clinuvel recently announced concrete plans to launch a non-pharmaceutical product line under private label in Europe and Asia in 2018e. These dermatological products should be complementary to Scenesse.

**The pipeline of the product portfolio may be convincing indeed, the communication strategy of the company is not. Not even the main slogan, “situational awareness”, has ever been properly explained in the corporate disclosure. In addition, no financial targets have ever been stated, and the investor relations section of the website occurs to us mainly as an alibi.**

### Strategic outlook

Central element of the corporate strategy is (1) to maintain “situational awareness”; (2) to leverage the melanocortin technology (Scenesse) knowledge; and (3) to lend more visibility to the Clinuvel brand.

For the management, maximising operating profitability does not seem to be of top priority.

### Investor relations effectively non-existent

Apart from these, for an outside investor de facto meaningless and well-worn phrases, no further strategic statements have recently been made by the company.

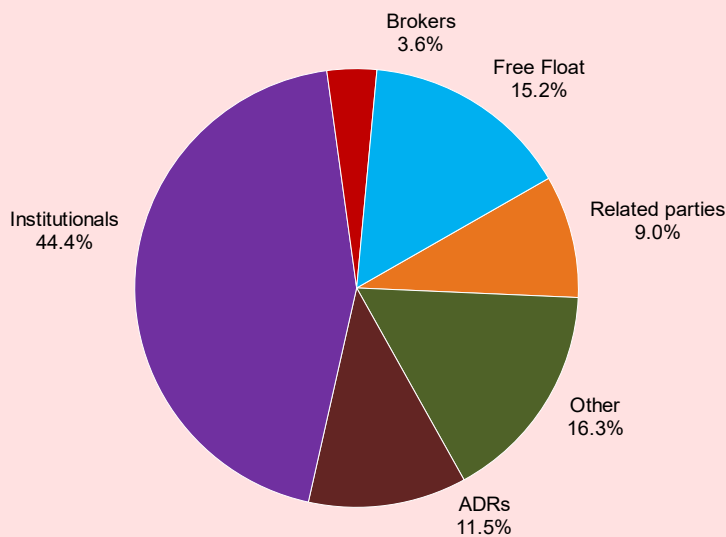
From our personal experience during the creation of this research report, management refrains from all communications activities, which typically should be considered a hygiene factor. There are no regular conference calls or quarterly presentations to investors or analysts. The subscription link to email updates, which the company offers to potential investors, is non-working. There is not even a responsible investor relations manager named on the website. Needless to say, there is also no working telephone number to anybody representing the company. Knowing this, it does not come as a surprise that the last analyst report (prior to this one) has been published in 2013, i.e. five years ago. This seems to be very strange for a global company with a market cap of more the AUD 330 mn.

**Clinuvel is led by an experienced and knowledgeable management team, whose CEO, for unknown reasons, has already announced that he is going to resign in 2021. There is no information about second level management available.**

**Institutional investors as the majority shareholder**

Currently, there are 47,735,227 ordinary shares on issue, and no dilution has occurred since last year. The largest shareholder group are institutional investors (44.4%) followed by related parties (9.0%). 11.5% of total shares outstanding are Sponsored American Depository Receipts (ADRs). Shareholdings of the management board and therefore the motivation of the board to maximize share price performance has not been disclosed yet.

**EXHIBIT 13: SHAREHOLDER STRUCTURE**



Within the institutional investors, well-known funds are invested, among them Fidelity (~10%) and Lagoda (~11%).

SOURCE: COMPANY DATA, SPHENE CAPITAL

**Experienced management team**

The core team of Clinuvel has been responsible for the turnaround of the company following the 2005 crisis. Currently, Clinuvel is led by a management team of three:

**🕒 Dr Philippe J. Wolgen (CEO)**

As a former equity analyst, Dr Wolgen joined Clinuvel in 2005: Prior to Clinuvel, Dr Wolgen held positions in private pharmaceutical companies in Europe, as MD of two medical centres in the UK and Israel, and consulted medical device companies. Dr Wolgen has been instrumental in raising external funds to finance Clinuvel during its unprofitable years. Dr Wolgen holds an MBA from Columbia University NY and the London Business School and an MD from the University of Utrecht. Dr Wolgen also acts as Non-voting member of Clinuvel’s Audit and Risk Committee and the Remuneration and

Nomination Committee.

**Dr Dennis J. Wright (Chief Scientific Officer)**

Dr Wright has more than 25 years of experience in the pharmaceutical industry. He worked more than 17 years at CSL where he acted nearly 10 years as Regulatory Affairs Manager. Before Dr Wright joined Clinuvel, he was also Global Pharmacovigilance Manager and Regulatory Affairs Manager for the Australian and New Zealand operations of Mayne Pharma. He has a Pharmacy degree and post graduate qualifications from the University of Sidney and Health Economics qualifications from Monash University, Melbourne.

**Darren M. Keamy (CFO)**

Darren M. Keamy is qualified as Certified Public Accountant (CPA). Before joining Clinuvel in 2005, Darren M. Keamy was in key management accounting and commercial positions at Amcor Limited, where he worked for a nine-years period. He is also experienced in financial regulation and control within the banking and retail pharmaceutical industries in the UK.

**Clinuvel is the sole owner of afamelanotide which was originally developed for skin cancer prophylaxis, but was never approved for this indication. In 2005, Clinuvel began to develop Scenesse as a dermatological drug, and in 2006 commenced a clinical program which focused on erythropoietic protoporphyria (EPP). The idea was to protect patients from EPP related symptoms by reducing the incidence and severity of phototoxic reactions.**

## EXHIBIT 14: OVERVIEW OF COMPANY HISTORY

<b>Corporate</b>	<b>2005</b> Repositioning of Epitan Ltd. (est. 1999) with focus on afamelanotide as a treatment in EPP		<b>2014</b> Hostile takeover bid from Retrophin			
<b>Europe</b>	<b>2010</b> Afamelanotide prescribed under Italian law	<b>2012</b> EMA marketing authorization application for Scenesse	<b>2012</b> Reimbursement of Scenesse in Switzerland	<b>2014</b> EMA marketing authorization for Scenesse under exceptional circumstances	<b>2016</b> First commercial treatment for EPP patients with Scenesse in Europe	<b>2017</b> Scenesse pricing in Germany agreed
<b>USA/RoW</b>						<b>2016</b> Agreement with FDA on New Drug Application timelines
<b>Financing</b>	<b>2006</b> Raise of AUD 40.2 mn via rights issue and private placement	<b>2007</b> Raise of AUD 26 mn via private placement	<b>2012</b> Raise of AUD 6.2 mn	<b>2013</b> Raise of AUD 6.3 mn	<b>2014</b> Raise of AUD 6.9 mn	<b>2016</b> Raise of AUD 8.3 mn

SOURCE: COMPANY DATA, SPHENE CAPITAL

### Company history

In the 1980s, afamelanotide was initially tested at the University of Arizona. Later in 1995, the private company Melanotan Inc. licensed afamelanotide for the use of a skin cancer prophylaxis but was never approved for this indication. In 1999, a new management formed the public company Epitan Ltd. and tried to turn afamelanotide into a cosmetic product under the name Melanotan, one that is used as a natural tanning preparation – but eventually failed as well. In 2006, after Epitan was renamed into Clinuvel, the company began to develop this technology, Scenesse, as a dermatological drug for individuals who suffer from visible and ultraviolet (UV) light intolerance. In 2006, Clinuvel commenced a clinical program which focused on erythropoietic protoporphyria (EPP). The idea was to protect patients from EPP related symptoms by reducing the incidence and severity of phototoxic reactions.

Between 2005 and today, clinical programs have also been conducted for individuals diagnosed with other disorders, including polymorphous light

eruption, solar urticaria and organ transplant recipients who are susceptible to an extremely high rate of skin cancers.

- Ⓢ **In 2009**, Clinuvel announced that it had expanded its pipeline to include a second drug candidate, named CUV9900, which is based on the same technology as Scenesse. As of today, CUV9900 is still in early stage development.
- Ⓢ **In 2010**, Scenesse became the first dermatological drug listed under the Italian law, allowing Italian physicians to prescribe Scenesse to EPP patients, while the costs of the drug are reimbursed by the Italian National Health System (Sistema Sanitario Nazionale, SSN).
- Ⓢ **Later in 2010**, Clinuvel announced that it would investigate Scenesse’s ability to repigment vitiligious skin.
- Ⓢ **In 2014** Scenesse was approved by European Medicines Agency (EMA) for the prevention of phototoxicity in adult EPP patients. In 2017, pricing in German was fixed. Scenesse is the standard of care for EPP in Germany, Austria, Switzerland, Italy, and the Netherlands.

**EXHIBIT 15: UPCOMING EVENTS**

<b>Europe/ Australia</b>	<b>2018e</b> Vitiligo results n=18 Asian phenotype	<b>2018e</b> EPP expert meeting Scenesse evaluation	<b>2018e</b> Physician initiated cutaneous porphyrias	<b>2018e</b> 2 <sup>nd</sup> annual report EMA	<b>2019e</b> Label extension Rx to 6 from 4 doses	<b>2020e</b> 1st PK trial in children n=5, 11-18 years old (Scenesse Enfants)
<b>Asia</b>	<b>2018e</b> Analytical lab in Singapore Regulatory support	<b>2018e</b> Launch of Clinuvel skincare solutions over 2 distribution channels	<b>2018e</b> Filing Scenesse for EPP, Japan		<b>2019e</b> CUV9900 PK study, Topical Rx	<b>2020e</b> First results CUV9900
<b>USA</b>	<b>2018e</b> 2 <sup>nd</sup> annual report to FDA	<b>2018e</b> FDA starts validation	<b>2018e</b> FDA decision on priority review	<b>2018e</b> Type C meeting FDA vitiligo protocol	<b>2018e/19e</b> FDA PDUFA V NDA or CRL	<b>2019e</b> 1st US EPP patient treated

SOURCE: COMPANY DATA, SPHENE CAPITAL



## Strengths and weaknesses, opportunities, and threats

We see the following company-specific **strengths** of Clinuvel:

### Strengths

- ⑤ **Focus on rare diseases EPP and vitiligo:** So far, Clinuvel specializes in the development, production, and marketing of pharmaceutical products in niche markets. Here, Clinuvel is considered to be the pioneer in photoprotective pharmaceuticals. The critical advantage of Clinuvel's product Scenesse is the fact that EPP is rare, competition is limited and Scenesse the is the only viable treatment option for EPP.
- ⑤ **Revaluation needed after FDA approval:** Clinuvel has announced to submit its NDA dossier to the FDA in February 2018. FDA decision can be expected by April 2019e at latest. If the FDA decided in favour of Clinuvel, the decision would unlock the access to approximately (according to our estimates) 4,000 EPP patients in the US. With estimated revenues per patient of USD 60-80,000 per year, this would eventually have a sales impact of USD 60-80 mn (25% penetration assumed).
- ⑤ **Underspending on innovation:** With the regulatory body forcing the pharmaceutical sector to focus on returns on investment in pharmaceutical development, Clinuvel benefits from costs significantly below industry averages: While the pharmaceutical sector spends an average of USD 1.2 bn on one pharmaceutical program, Clinuvel managed to launch Scenesse at costs of under USD 125 mn. Underspending could have also been the result of research studies with a small number of human participants – which would not be possible for Clinuvel to repeat in the future, though.
- ⑤ **Lifetime patient relationships:** Due to the incurability of EPP, patient relationships are of a decidedly long-term nature. Theoretically, it is possible that a hospital or physician in charge discontinues the use of Clinuvel's medicinal products, but this has happened only rarely to date, according to the company.
- ⑤ **Expansion into new products and segments:** Apart from EPP and vitiligo, Clinuvel has built a knowledge domain around photomedicine and skin pigmentation that is likely to be expanded over the coming years to further applications, also with substantially less regulatory schemes.
- ⑤ **A (theoretically) broad market penetration:** With a total number of 42 expert centres now in place, patient access is going to significantly improve especially in Germany, Italy, Austria, and the UK in our view. With only one and two expert centres in France and Spain, however, Clinuvel should increase penetration in these countries.
- ⑤ **Highly profitable company:** High research and approval expenses have prevented Clinuvel from making its business model profitable over a long period of time. The cumulative operating loss incurred over the years 2001-16 was AUD -137.0 mn. Business activities have mainly been financed from capital increases, which have been used to collect a total of AUD 95 mn so far. Only in 2017, when the commercialization phase of drug development has been reached, Clinuvel turned profitable with EBIT of AUD 7.1 mn, 11 years since the start of its EPP program. According to our estimates, Clinuvel should be independent on equity funding from external resources from now on.

We see the following company-specific **weaknesses** of Clinuvel:

### Weaknesses

- ⑤ **Highly unusual investor relations policy:** Clinuvel's investor relations policy does not match a company of its size or reputation, in our view. One seekingalpha blogger recently even raised the question "if Clinuvel management is obsessed with linguistic smoke bombs." Apart from an almost obsessive trend to formulate corporate news as deterring as possible, (1) the management does not provide regular conference calls or quarterly presentations to investors or analysts; (2) quarterly reports are somewhere hidden among countless press releases; (3) the subscription link to email updates, which the company offers to potential investors, is non-working – even weeks after the company had been informed about the glitch; (4) there is not even a responsible investor relations manager named on the website.

Needless to mention, there is also **(5)** neither a financial calendar on the website nor **(6)** a working telephone number to anybody representing the company on the website. Knowing all this, it does not come as a surprise that **(7)** the last analyst report (prior to this one) has been published in 2013, i.e. five years ago. Flying below the radar screen seems to be highly unusual for a profitable pharmaceutical company such as Clinuvel, given its current market cap of more than AUD 330 mn.

- ⑤ **Management seems to consider takeover bids as a threat:** At the same time, Clinuvel appears to be maintaining intensive investor relationships with selected institutional investors, with some of them the company appears to collaborate on an exclusive basis, in our view. Our impression is that the company prefers to have strong strategic anchor investors rather than a free-float pool that, in another takeover bid, could seize the opportunity and tender their shares.
- ⑤ **Shareholders are only one among many stakeholders:** Knowing the dissatisfying IR policy it does not come as a surprise that Clinuvel considers investors as one of no less than 15 stakeholder groups (which have been further differentiated into no less than 40 subgroups) to which the company provides relations management. Communication with such a number of stakeholder groups requires considerable management attention.
- ⑤ **Lengthy approval procedures:** 12 years after Clinuvel started the dialogue with the FDA and eight years after Clinuvel obtained orphan drug designation for Scenesse, the agency provided the filing pathway through a Fast Track designation and assessed Clinuvel to be ready for filing its dossier for EPP. Approval procedures are more time consuming than usual, since many payors have been unaware of the need to treat EPP patients due to the rarity of the disease.
- ⑤ **Missing own deadlines:** In our view, management of Clinuvel has the tendency to miss their own timelines, even very close to expected completion – even if they don't appear overly ambitious. The latest example was the delay of the FDA approval timeline for Scenesse on EPP.
- ⑤ **Expert centres have some downside too:** Clinuvel has restricted the product's availability only to those expert centres who have worked with EPP patients. In addition, training, and accreditation necessary to comply with the demands of the national and European authorities are a lengthy process.
- ⑤ **Uncertainty about FDA approval:** While Clinuvel seems to make progress with the FDA on market access for Scenesse EPP in the US, there is no guarantee for an approval. Should the FDA reject Scenesse as an EPP treatment in the US, Clinuvel would miss two thirds of our estimated total revenues, which would imply a substantial downside to our price target.
- ⑤ **Safety profile of Scenesse:** The introduction of Scenesse in Europe is currently accompanied by strict documentation obligations for doctors and patients to gain additional safety data. Any safety concern could delay extension of the product to other applications, or might in an extreme case lead to a stop of distribution.
- ⑤ **Risks arising from upscaling of the company:** Turning Clinuvel from a research driven company into a commercial global entity entails certain organizational risks, which could endanger the profitability of the company.
- ⑤ **Vitiligo risk:** Growth from vitiligo might not materialize as expected, because a systemic treatment (injection) may not respond properly to the local spots of non-pigmented skin properly. So, if Clinuvel fails to develop a suitable application (be it an injection or topical), this source of growth would vanish.
- ⑤ **Organizational risks:** Clinuvel could not be able handle the complexity of organizational growth and could fail to manage the high-resource R&D and study work necessary for all the new applications. After all, Clinuvel is still a small company with substantially less than 100 employees, according to our estimates. In addition, with Clinuvel gradually progressing from a clinical development-focused company into a commercially focused company, Clinuvel will most likely suffer from new and increased management

responsibilities.

- Ⓢ **Slight seasonality of revenue generation:** The treatment characteristic of Scenesse provides a seasonality to its peak use. During months with increasing light intensity the risk of anaphylactoid reactions, burns and aversion of outdoor exposure by EPP patients is magnified. Therefore, product distribution is strongest during eight months of maximum risk, however, this effect should be more and more balanced on a global basis.

The **opportunities** described below apply to all companies active in the same industries as Clinuvel:

## Opportunities

- Ⓢ With the emergence of specialty treatments and orphan drug companies, we anticipate a growing sentiment in favour of pharmaceutical companies entering a market where little competition existed by virtue of lack of available treatment.
- Ⓢ **Increasing regulatory requirements** provide the basis for a structural and sustainable market growth. In addition, due to the regulated character of the business, barriers to entry for potential competitors are high.
- Ⓢ The high research intensity of the business model and the need for EU-wide approval create **high market-entry barriers**. Further barriers are discernible on the medical side, where customer relationships tend to be long-term due to protracted bureaucratic approval procedures.
- Ⓢ **Potential takeover speculation:** As a debt-free small cap, which moreover might be on the verge of a potential turnaround, the company is, in our view, basically an acquisition target for big, globally active pharmaceutical companies, which are continuously searching for approved, patent-protected medicinal products. In 2014, Clinuvel received an unsolicited USD 95 mn takeover offer from drug company Retrophin, then run by controversial Martin Shkreli.

The **threats** described below apply to all companies active in the same industries as Clinuvel:

## Risks

- Ⓢ **Cost reimbursement:** If costs were no longer covered by health insurance companies, we would expect a significant impact on the demand for Scenesse and/or its pricing.
- Ⓢ **“Daraprim effect”:** Several prominent US pharmaceutical companies have managed to attract negative attention from press, politicians and public for their marketing and pricing practices for pharmaceutical products and healthcare technologies, even for outdated pharmaceuticals such as Turing Pharmaceutical’s Daraprim. This may eventually spill-over to medical innovation driven companies.
- Ⓢ **Little market power:** As a small enterprise, Clinuvel has to stand its ground in the market among significantly larger international pharmaceutical groups with much more financial power.

## Basics of the Human Skin

With a surface area of 1.5 to 2.0 m<sup>2</sup> (adults) human skin is the largest organ of the human body. It is characterised by a low permeability and thus provides a physical barrier to water and other fluids, pathogens, and UVR. Skin protects the human body from mechanical, chemical, and microbial damage. Potential skin disfunction or damage by contrast, induces water loss, dehydration, infections, and inflammations.

### Human skin is the largest organ of the human body ...

Human skin is the largest organ of the human body, with its surface ranging from 1.5 to 2.0 m<sup>2</sup> (adults). Its thickness varies considerably over the various parts of the human body depending from sex and age. Skin is the outmost organ of the body and is essential also for our physical appearance. Other conclude about our physical state, mood, and attractiveness upon the appearance of our skin. Skin flora, for the most part, consists of bacteria. There are around 1.000 distinct species of bacteria, mainly in the upper parts of the human skin, which, despite various efforts, cannot be removed by any amount of cleaning.

### ... which serves various functions

Skin protects the human body from mechanical, chemical, and microbial damage. However, its various functions are much broader and can be described as follows:

Various skin functions

- ⑤ **Immunologic protection:** Human skin does not only sense but also responds to pathogens from the environment; a potential disfunction could lead to infections, skin cancer, inflammation, and allergies.
- ⑤ **UVR protection:** Skin pigmentation, foremost the dark skin pigment melanin, preserve cells from damaging by UV radiation. In addition to melanin, a couple of other UV protecting pigments are located in the different layers of the skin.
- ⑤ **Temperature regulation:** Skin regulates the body temperature. Fat and hair, which are harboured in the skin, isolate the body against coldness whereas sweat production accelerates heat loss. In addition, skin is highly provided with blood. While dilated blood vessels support perfusion and heat loss, restricted blood vessels reduce cutaneous blood flow and conserve heat.
- ⑤ **Sensation:** Skin contains various nerve endings, which constantly monitor the external environment and react to heat, cold, touch, injury etc.
- ⑤ **Appearance and human communication:** Skin displays our mood, physical state, and attractiveness. Therefore, skin defects can result in considerable psychological distress.
- ⑤ **Evaporation control:** Skin provides a barrier to fluid loss. Massive fluid loss could be an emergency in case of severe burns.
- ⑤ **Absorption:** In principal, skin has low permeability. Most (damaging) external substances cannot penetrate and diffuse through skin. However, external oxygen may diffuse through skin as well as certain nanoparticles, which can be administered through skin for medical purpose for example.
- ⑤ **Storage and synthesis:** Skin is as a storage centre for lipids and water. With the help of sunlight Vitamin D is synthesised in the skin.

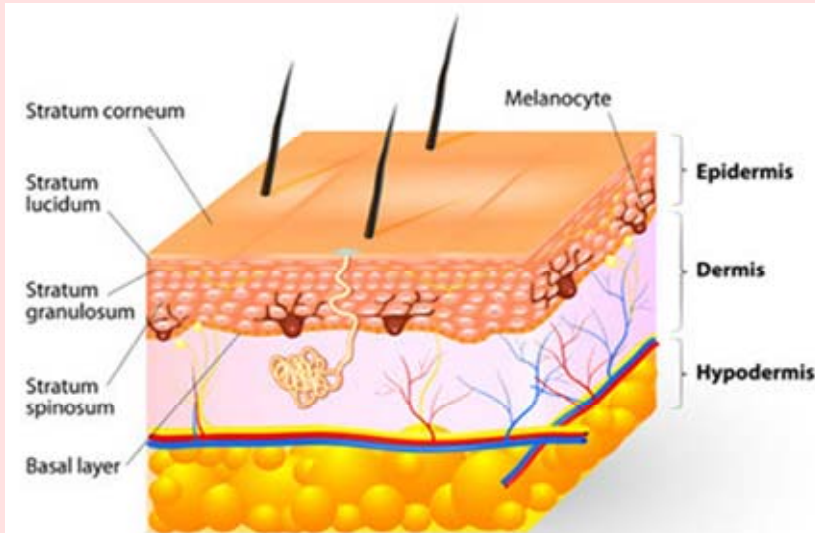
### Structure of the skin

The various functions of the skin are performed by different layers. There are three principal layers, which are named from the outer to the inner (1) the epidermis, (2) the dermis and (3) the hypodermis (subcutis):

- ⑤ **Epidermis:** "epi" is Greek and means "over" or "upon". The epidermis is the outmost layer of the skin and consists primarily of keratinocytes. The epidermis contains no blood vessels and is almost exclusively nourished by diffused oxygen from the external environment.
- ⑤ **Dermis:** The dermis lies below the epidermis. It consists of fibroblasts, collagen, and elastic fibres. It harbours many nerve endings as well as blood vessels and various glands (sweat, tallow, etc.).
- ⑤ **Hypodermis (also subcutis):** The hypodermis, also known as subcutis, is

located below the dermis and is not part of the skin in a narrow sense. However, it attaches the skin to the underlying bones and muscles and supplies blood vessels and nerves. Fifty percent of the body fat are stored within the hypodermis, which therefore also serves as an important padding and isolation.

## EXHIBIT 16: MAIN LAYERS OF THE SKIN



The various layers perform multiple and distinct functions of the skin.

SOURCE: DOTERRA

### Epidermis – multifunctional barrier and protection

The epidermis forms a waterproof, protective wrap over the human body. The epidermal cells are formed through mitosis in the basal layer of the epidermis, where nutrient supply from the underlying layers is still good. During a two-week life-cycle the cells move up from the basal layer to the so-called stratum spinosum and further to the stratum granulosum until they reach the stratum lucidum and stratum corneum. During this journey the cells gradually change their shape and composition until they finally die.

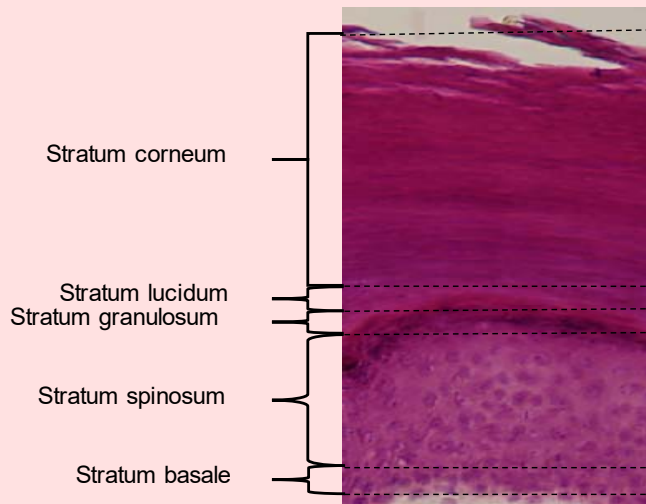
Around 90% of the epidermal cells are keratinocytes. They are held together by desmosomal junctions which are responsible for the “spiny” appearance of the stratum spinosum. Lipids produced and secreted by the keratinocytes provide a water barrier in the skin. As the cells move up the epidermis, cytoplasm is released, and the protein keratin is inserted (keratinisation). In the stratum corneum the cells desquamate. The thick outer layer of the flattened, keratinized, and non-nucleated cells forms a barrier against external infections and traumas.

In addition to **keratinocytes**, three additional main types of cells can be found in the epidermis:

- ⑤ **Langerhans cells** are dendritic (antigen presenting cells), which are found in all layers of the epidermis, mainly in the stratum spinosum. They provide for the recognition, uptake, processing and presentation of antigens to sensitised T-cells.
- ⑤ **Merkel cells** are mechanoreceptors for light touch sensations located in the basal layer of the epidermis. Most often they are associated with sensory nerve endings and abundant in highly sensitive skin areas like the human fingertips.
- ⑤ **Melanocytes** are also located in the basal layer and staggered around one in every 10 keratinocytes. Melanocytes are responsible for the production of the dark pigment melanin in a process called melanogenesis. Melanin is primarily responsible for the colour of the skin (and eyes and hair) and is protecting the subcutis from UVR and potential DNA photodamages. Different skin colours from lightly to darkly pigmented individuals are, however, not due to the

quantity of melanocytes, but to different levels of the melanocytes' activity, which is under hormonal control.

#### EXHIBIT 17: VARIOUS LAYERS OF THE EPIDERMIS



The epidermis is an internal and external permeability barrier. In addition, it protects from UVR and pathogens and provides thermal protection, sensation and (wound) regeneration.

SOURCE: AMERICAN ACADEMY OF DERMATOLOGY, SPHENE CAPITAL

#### The dermis – elasticity and wound healing

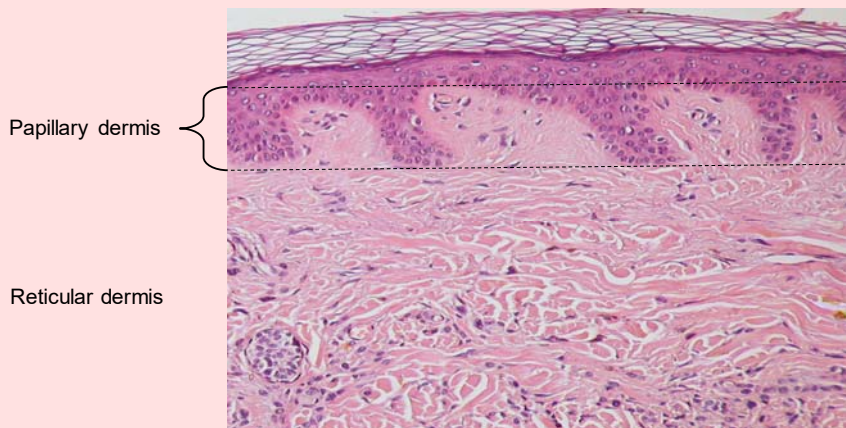
The dermis is the layer of skin beneath the epidermis. It is tightly connected to the epidermis and provides a tough and flexible support structure. The dermis is much thicker than the epidermis as it contains blood and lymphatic vessels, hair follicles and sweat glands. The Blood vessels in the dermis are responsible for the nourishment and waste removal from both its own cells and from the cells in the basal layer of the epidermis.

The dermis has two sublayers. The papillary dermis, located under a basement membrane between the epidermis and the dermis, is characterized by an areolar connective tissue. It is named after the papillae, finger like projections, which extend towards the epidermis and strengthen the connection between the dermis and the epidermis. The reticular dermis beneath, got its name from the dense concentration of collagenous, elastic, and reticular fibres.

The main cells types in the dermis are:

- ⑤ **Fibroblasts** which are responsible for the synthesis and degradation of the extracellular matrix and collagen, thus for the maintenance of the connective tissue. In case of tissue damage and injuries less active fibroblast cells (fibrocytes) get stimulated and are responsible for wound healing.
- ⑤ **Mast cells** are part of the immune system and are directly involved in wound healing, angiogenesis, immune tolerance and pathogens defence.
- ⑤ **Adipocytes**, also known as fat cells, are responsible for the composition of the adipose tissue which provides for energy storage, cushioning and protection. In addition, it enables the mobility of the skin over the underlying structures.

**EXHIBIT 18: LAYERS OF THE DERMIS**



The dermis protects the body from pathogens and serves as thermo-regulation, wound regeneration and provides for sensation.

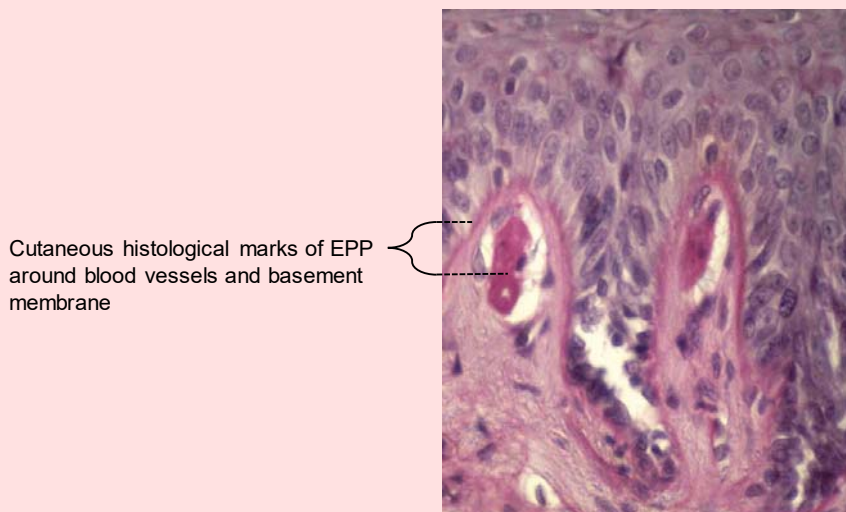
SOURCE: AMERICAN ACADEMY OF DERMATOLOGY, SPHENE CAPITAL

**The hypodermis – isolation and cushioning**

The hypodermis or subcutis, Latin word for “beneath the skin”, is the fat layer of the skin. As such the hypodermis not only separates the dermis from the underlying structures, i.e. muscles and fascia, but it also serves as an energy supply as well as it cushions and isolates the body and finally allows for the mobility of the skin over the underlying structures. The hypodermis contains larger blood vessels and nerves than the dermis.

The main cells types in the hypodermis are similar to those which can be found in the dermis, namely fibroblasts, mast cells and adipocytes.

**EXHIBIT 19: MANIFESTATION OF EPP**



EPP is clinically characterized by photosensitivity to visible light commencing in childhood, and biochemically by elevated red cell protoporphyrin levels (Todd, 1994).

SOURCE: LECHA ET AL; LICENSEE BIOMED CENTRAL LTD. 2009, SPHENE CAPITAL

**Cutaneous photosensitivity – an inborn but rare disease**

Erythropoietic protoporphyria (EPP) is classified as so called “rare disease”, which by definition of the European Union affect less than 1 in 2,000 people of the general population. It is a form of cutaneous photosensitivity to visible light usually commencing in early childhood and remaining for life.

EPP is a form of cutaneous photosensitivity

EPP patients suffer from tingling, burning, itching and pain within minutes of light exposure, which might also be followed by swelling and redness (erythema). The

symptoms vary based on the intensity and duration of the sun exposure. Pain might be severe and not alleviated by narcotic analgesics and can persist for hours or even days after the initial phototoxic reaction. In addition, individuals are not only sensitive to direct sunlight but also to sunlight that passes through window glass and artificial light (including surgical lights).

Multiple episodes of acute photosensitivity may lead to chronic changes of the exposed skin like lichenification, leathery pseudovesicles and grooving around the lips. Approximately 20 to 30% of the affected individuals do also suffer from some degree of liver dysfunction, which is typically mild; up to 5% however, may develop more advanced and even life threatening liver disease.

#### **EPP – pathogenesis**

Erythropoietic protoporphyria (EPP) is a form of cutaneous photosensitivity to visible light, whose clinical manifestations have already been described. They are caused by excessive levels of protoporphyrin in various tissues, mainly within red blood cells, plasma and the liver. The accumulation of protoporphyrin is caused by an inborn error of protoporphyrin metabolism because of a decreased activity (<30% of normal) of the enzyme ferrochelatase. Ferrochelatase catalyses the insertion of iron into protoporphyrin to form heme. A decreased activity of ferrochelatase, by contrast, causes an increased concentration of free protoporphyrin.

Protoporphyrin has some specific characteristics: It is hydrophobic but lipophilic and light absorbing. As protoporphyrin accumulates in the various tissues (red blood cells in skin blood vessels) it there absorbs light between 320 and 595 nm. The absorption of light increases the energy content of the protoporphyrin, which transfers the excess energy to oxygen (O<sub>2</sub>). The activated oxygen interacts with lipids, proteins etc. and causes the described photosensitive reactions.



## Financial forecast (EPP case)

Clinuvel generates mostly transaction-dependent revenues. The cost side is dominated by staff expenses. In the past fiscal year 2016/17, with only approximately 265 EPP patients, the company managed to turn profitable and boosted EBIT margins to 41.9% from negative territories. This gave a first indication which regions the profitability could reach once a global roll-out of Scenesse has been achieved. For the current fiscal year, we expect another substantial revenue and earnings leap and calculate revenues and EBIT of AUD 46.3 mn (+172.8% YoY) and AUD 22.5 mn, respectively. This is due to a further market penetration solely of EPP and a substantial increase in average number of treatments per patient. By the end of our detailed-planning phase in 2020/21e, we anticipate a substantial increase in revenues and EBIT to AUD 409.1 mn and AUD 243.5 mn, respectively, reflecting operating margins of 59.5%.

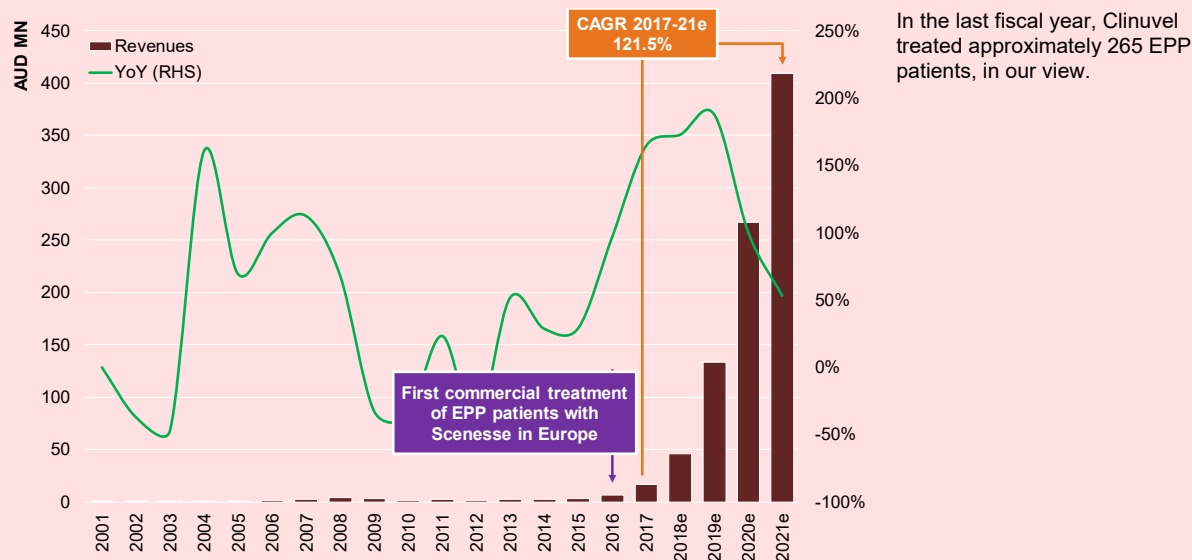
Our forecast is based on EPP only. Neither vitiligo nor topical products or neurodegenerative products have been considered due to a lack of transparency about their potential impact. We therefore consider our forecast a worst-case model.

### Clinuvel generates transaction-dependent revenues

Clinuvel bills its customers – mainly hospitals and private practices – once implants have been delivered to the dermatologist in charge. In fiscal year 2016/17 (30/06), the company generated revenues of AUD 17.0. This corresponds to revenue growth rates of 164.6% versus the previous fiscal year, in which Clinuvel posted revenues of AUD 6.4 mn. Given revenues of AUD 2.5 mn reported in Clinuvel's 2013/14 results, compound annual growth rate over the period 2013/14-16/17 were 88.7%.

We are looking for a significant increase in Clinuvel's average annual revenue growth rates since the company has been granted EU-wide approval and cost reimbursement. Based on this assumption, we see Clinuvel generate revenues of AUD 409.1 mn by the end of 2020/21e. This corresponds to an average annual growth rate (CAGR) of 121.5% in the 2016/17-20/21e period.

EXHIBIT 20: REVENUES AND REVENUE GROWTH



SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

### Revenue assumptions in detail

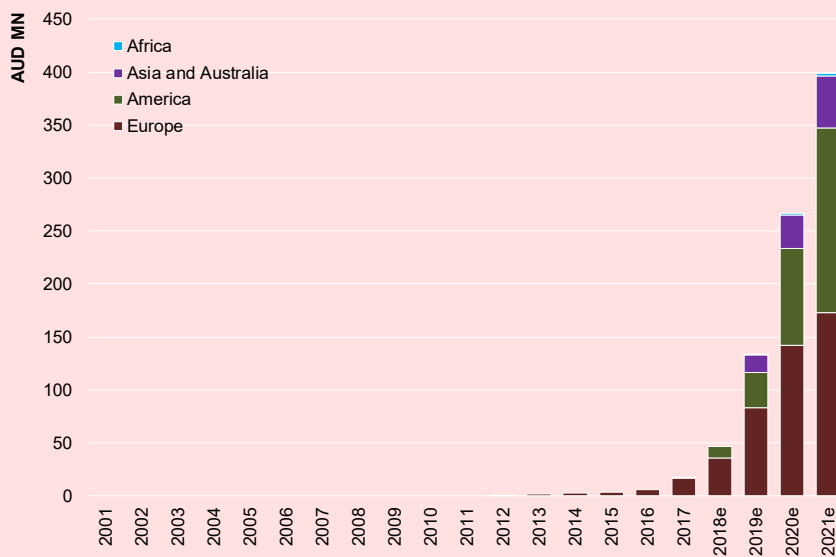
Our most cautious revenue forecast is based upon the following assumptions:

- ⑤ Our revenue forecast is based on the worldwide number of registered EPP patients (for details see annex). According to our analysis, there are approximately 6,800 registered EPP patients. We deliberately chose to use

the registered number of EPP patients instead of the statistical data of EPP prevalences, which would result in substantial higher EPP patient numbers of between 25,000 (prevalence 1:200,000) and 67,000 (1:75,000).

- ⑤ According to Clinuvel, price points per EPP patient are between EUR 56,400 and EUR 84,600, depending on the number of treatments per year. We have assumed that in the beginning, 50% of patients will opt for the higher number of treatments, 50% for the lower number of treatments. Over the course of the years, this ratio subsequently changes to 60%-40%. In our model, average costs per patients calculate for EUR 70,505 in the beginning and EUR 73,325 in later years.
- ⑤ We applied EURAUD of 1.5270.

**EXHIBIT 21: REVENUES BY REGION**



Our growth rate forecast is based on a mix of domestic and international growth. In Europe, we project an average annual growth rate of 82.1% during our 2016/17-20/21e forecast period. Revenues in the US should speed up when FDA approval has been obtained, which we expect to happen in 2018e.

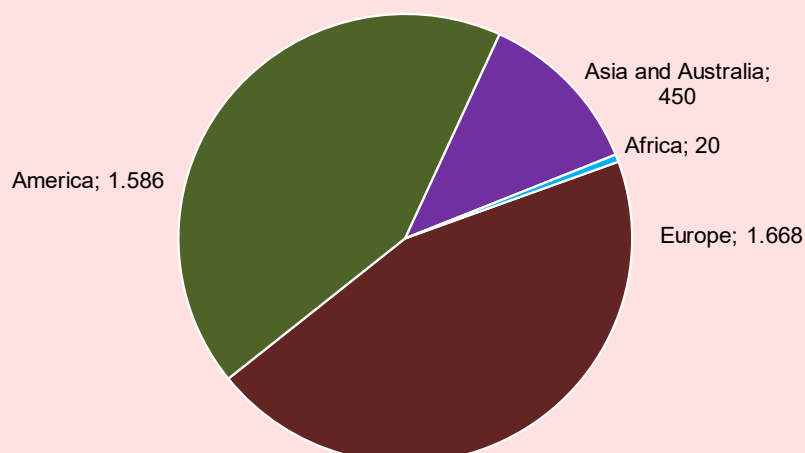
SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

**Growth driver: Rising number of implants**

We expect the company's revenue growth will be boosted by only one driver: total number of implants. Prices are expected to remain constant. We estimate that Clinuvel treated 265 EPP patients in the last year.

With more and more countries to complete the assessment of Scenesse, total number of patients will substantially increase over the years to come. We forecast an increase of annual treated patients to 3,724 (CAGR 2016/17-20/21e 93.6%) by the year 2021e. The following chart shows the expected geographical distribution of the patients treated by Clinuvel.

EXHIBIT 22: EPP TREATMENTS IN 2020/21E



SOURCE: SPHENE CAPITAL FORECASTS

### R&D and commercialization expenses are of major P&L importance

After gaining the European Medicine Agency's (EMA) marketing authorization for Scenesse in erythropoietic protoporphyria, the company continued to implement a post-authorization program to monitor patient safety and product effectiveness (post-authorization safety study PASS) and the training and accrediting of hospital sites in the collection of data and use of Scenesse. In the US, Clinuvel focused on the NDA submission under a rolling review basis for Scenesse, while the R&D program was concentrated on the Singapore Phase II clinical study in vitiligo and on the formulation work for its topical applications (CUV9900 and VLRX001).

R&D and commercialization expenditures which include clinical study costs, drug formulation R&D, manufacturing and distribution, regulatory fees and research, development, and commercialization overheads such as personnel, rose from 18.4% to 40.4% of total expenses from 2014/15 to 2016/17, respectively.

- ⑤ **Clinical study costs** decreased by 2.3%, since Clinuvel focused on the commercialization of Scenesse in Europe and its regulatory activities in the US.
- ⑤ **Expenses for drug formulation, R&D, manufacturing, and distribution** which reflect the implant production costs, increased by 127.1%, from AUD 0.450 mn in 2014/15 to AUD 1.022 mn in 2015/16 but decreased to AUD 0.857 mn in 2016/17. One-off distribution set-up costs which occurred in 2015/16 more than outweighed a continuing increase in product manufacturing costs.
- ⑤ **Regulatory related costs and non-clinical development costs** increased slightly by 3.3% from AUD 0.973 mn to AUD 1.005 mn. They mainly reflected costs to establish the regulatory infrastructure for Scenesse in Europe and to meet the post-authorization commitments including pharmacovigilance oversight and safety reporting systems, post-authorization safety studies and regulatory agency fees. However, the increase in regulatory related costs was offset by the cessation of expenditures for the pre-clinical chronic toxicology study.
- ⑤ **Clinical, regulatory, and commercial overhead costs** were strongly up from AUD 1.606 mn to AUD 2.061 mn from 2015/16 to 2016/17. Additional recruitment to oversee and monitor the clinical, regulatory, and manufacturing/post-marketing programs were responsible for the increase as well as first time royalty fees for the implant manufacturing.

### About half of total expenses stem from expenses for general operations

The transparent the company is with regard to R&D and commercialization expenditures, the opaque the company is with regard to expenses for general

operations. This means that roughly half of total expenses will not be explained. In addition, general expenses have proven to be highly volatile in the past, since they include the expensing of the accounting valuation of share-based payments: To give an example, the expenses decreased to AUD 5.6 mn in 2015/16 from AUD 10.5 mn in 2014/15.

**We expect a significant decline R&D and commercialization expenses ...**

Our estimate for R&D and commercialization expenses in 2017/18e of AUD 9.3 mn yields a ratio of 38.5% of total expenses and 20.1% of net sales (previous year: 40.5% and 23,9% respectively). Expenses for drug formulation, R&D, manufacturing, and distribution in addition to clinical, regulatory, and commercial overhead account for approximately AUD 5.0 mn of the increase, in our view.

Increase in manufacturing-related expenditures from producing implants available for supply

**... and general operation expenses as a percentage of revenues**

The general operation expenses item mainly subsumes the accounting valuation of share-based payments and costs incurred by the expansion of the business. With the globalization of the business, we expect an increase of general operations costs to AUD 68.0 mn. Total expense ratio, however, is expected to decline to 41.3% in 2020/21e from 58.9% in 2016/17.

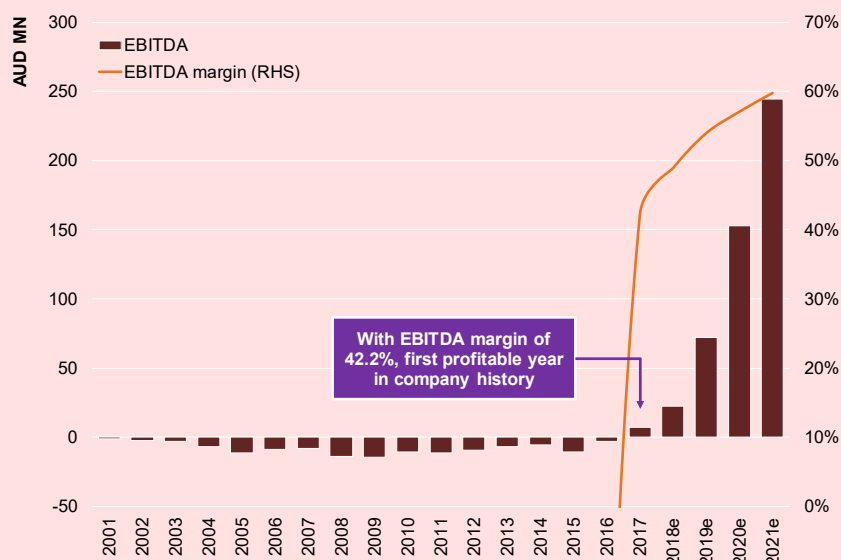
**Significant improvement in EBITDA and EBIT**

Clinuvel's 2016/17 EBITDA came to AUD 7.2 mn and turned positive for the first time in corporate history. This compares to a loss of AUD -3.2 mn in 2015/16. We are looking for a further significant improvement in operating EBITDA, to AUD 22.7 mn in the current fiscal year, followed by a marked earnings leap in the years to come. This is due to a further market penetration solely of EPP. Further treatments for diseases other than EPP were not taken into account.

By the end of our detailed-planning phase in 2020/21e, we anticipate a further increase in EBITDA to AUD 244.8 mn. On the basis of the company's overall performance, this corresponds to EBITDA margins of 59.8% (previous fiscal year 42.2%).

As of our model, EBIT is to move-up in line with EBITDA from AUD 7.1 mn in 2016/17 to AUD 22.5 mn in 2017/18e and to AUD 243.5 in 2020/21e reflecting margins of 41.9%, 48.6% and 59.5% respectively.

**EXHIBIT 23: EBITDA AND EBITDA MARGIN**



Our expected increase in earnings will mainly be fuelled by the revenue growth we anticipate and the associated economies of scale of major costs items. Once FDA approval has been granted, EBITDA should continue to improve following substantial sales in the US.

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

**Earnings before tax on a similar trajectory as EBITDA**

Clinuvel is a debt-free company. Our financial-planning does not include any financing costs. By contrast, we expect that Clinuvel to significantly increase cash flows after becoming cash flow positive in 2016/17. According to our model, EBT

including positive interest incomes will be up from AUD 7.1 mn in 2016/17 to AUD 22.8 mn in 2017/18e and to AUD 246.0 mn in 2021/22e.

Clinuvel has not recognized deferred tax assets with regard to unused tax losses in the past. Due to high tax-loss carry forwards of AUD 125.8 mn (2016/17) we have assumed that Clinuvel will not be charged before 2020/21e.

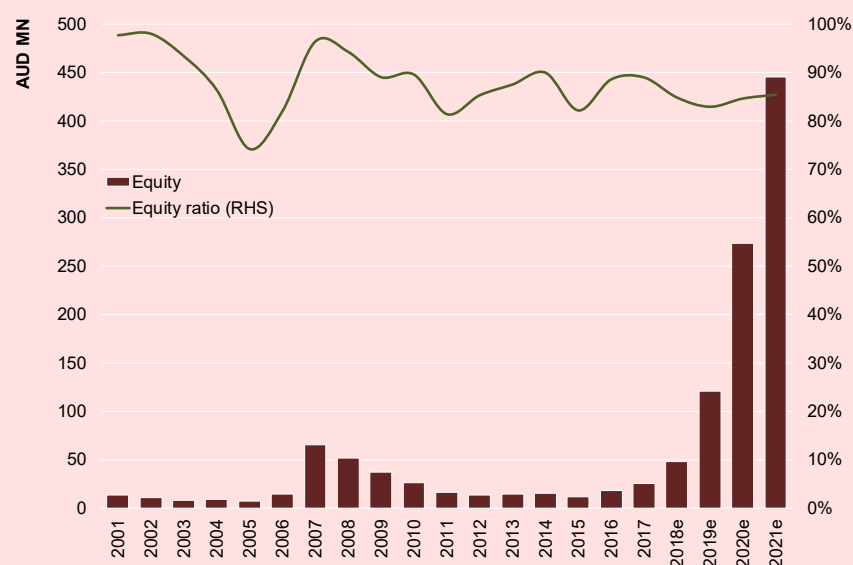
### Net annual income and earnings per share

We arrive at net annual income forecast of AUD 22.8 mn in 2017/18e rising to AUD 172.2 mn by 2020/21e. Based on 47.7 mn shares, our projections translate into earnings per share (EPS) of AUD 0.48 in 2017/18e. Our EPS projection for the end of our planning period in 2021/22e is AUD 3.61.

### Shareholders' equity within a comfortable range

Due to losses incurred in the past, a number of capital increases were necessary to secure additional working capital needs. Back in 2015/16, Clinuvel's shareholders' equity was raised by a total of AUD 8.3mn. These measures have kept the equity ratio of the company, which is debt-free from a gross perspective, consistently north of the 80% mark since 2005/06. At the end of the last fiscal year, the equity ratio stood at 88.6%.

**EXHIBIT 24: SHAREHOLDERS' EQUITY AND EQUITY RATIO**



Since the IPO in 2001, various capital increases have been required to prevent the company from becoming overindebted. In 2017, Clinuvel generated the first positive cash flow in its corporate history.

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

### 2016/17 was the first year of positive cashflows

While the Q1/2016/17 (ending 30 September 2016) was a quarter in which Clinuvel was still building up distribution in some countries, it was also the first quarter in company history when free cashflow were positive with AUD 3.5 mn, which is an impressive 61.8% of the quarters AUD 5.7 mn of revenues. This proves that Clinuvel has made the transition from a cash-burning biotech start-up to a commercial operation with sufficient cash-flow for self-funded growth, in our view.

### We do not expect any dividends in the foreseeable future

Due to the lack of profitability, Clinuvel did not distribute any dividends to shareholders in the past. Even after breaking even – an event that occurred in 2016/17 – investments in the company's future growth will, in our view, clearly take precedence over profit appropriation. We therefore do not expect the company to pay out any dividends in the period after 2020/17 either, but regard retention of the profits generated as the more likely scenario.

Clinuvel is unlikely to pay dividends during our forecast horizon through 2020/21e.

### Return on equity to turn positive for the first time in 2016/17

With 28.0%, Clinuvel has generated positive returns on equity (ROE) for the first time in 2016/17. For the current fiscal year, we estimate Clinuvel's ROE to

improve to 47.3%, which would correspond to an improvement of 1930 basis points versus the previous year.

**EXHIBIT 25: ROE COMPONENTS (DUPONT SCHEME)**

	2010	2011	2012	2013	2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>Net margin</b>	<b>-624%</b>	<b>-501%</b>	<b>-755%</b>	<b>-346%</b>	<b>-219%</b>	<b>-319%</b>	<b>-49%</b>	<b>42%</b>	<b>49%</b>	<b>54%</b>	<b>57%</b>	<b>42%</b>
EBIT margin	-624%	-501%	-755%	-346%	-219%	-319%	-49%	42%	49%	54%	57%	60%
Interest expense	100%	100%	100%	100%	100%	100%	100%	100%	101%	101%	101%	101%
Taxes	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	70%
<b>Asset Turnover</b>	<b>6%</b>	<b>11%</b>	<b>8%</b>	<b>12%</b>	<b>15%</b>	<b>24%</b>	<b>32%</b>	<b>59%</b>	<b>82%</b>	<b>92%</b>	<b>83%</b>	<b>78%</b>
<b>Leverage</b>	<b>112%</b>	<b>123%</b>	<b>117%</b>	<b>114%</b>	<b>111%</b>	<b>122%</b>	<b>113%</b>	<b>112%</b>	<b>118%</b>	<b>121%</b>	<b>118%</b>	<b>117%</b>
<b>ROE</b>	<b>-44%</b>	<b>-70%</b>	<b>-72%</b>	<b>-49%</b>	<b>-36%</b>	<b>-93%</b>	<b>-18%</b>	<b>28%</b>	<b>47%</b>	<b>60%</b>	<b>56%</b>	<b>39%</b>

SOURCE: SPHENE CAPITAL FORECASTS

**Management guidance**

In the past, the Management Board of Clinuvel has not disclosed a management guidance. We do not expect this to change in the near future.

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## Profit and loss statement, 2006-13

		2006	2007	2008	2009	2010	2011	2012	2013
<b>Gross sales</b>	<b>AUD Mio.</b>	<b>1.2</b>	<b>2.6</b>	<b>4.3</b>	<b>2.9</b>	<b>1.8</b>	<b>2.3</b>	<b>1.3</b>	<b>2.0</b>
YoY	%	100%	113%	68%	-32%	-36%	23%	-43%	52%
Material expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
in % of total net sales	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Gross profit</b>	<b>AUD Mio.</b>	<b>1.2</b>	<b>2.6</b>	<b>4.3</b>	<b>2.9</b>	<b>1.8</b>	<b>2.3</b>	<b>1.3</b>	<b>2.0</b>
in % of total net sales	%	100%	100%	100%	100%	100%	100%	100%	100%
<b>Expenses</b>	<b>AUD Mio.</b>	<b>-9.8</b>	<b>-10.7</b>	<b>-18.1</b>	<b>-17.4</b>	<b>-12.7</b>	<b>-13.6</b>	<b>-11.0</b>	<b>-9.6</b>
in % of total net sales	%	-818%	-419%	-421%	-600%	-685%	-597%	-850%	-491%
Clinical development	AUD Mio.	-1.1	-1.0	-1.5	-2.3	-2.6	-2.6	-1.8	-1.4
Drug formulating R&D	AUD Mio.	-2.7	-2.3	-5.0	-6.2	-3.0	-2.5	-1.0	-0.9
Regulatory and non-clinical	AUD Mio.	-1.6	-0.5	-0.8	-0.3	-1.0	-0.8	-0.5	-0.5
Clinical, regulatory and commercial	AUD Mio.	0.0	-0.8	-1.1	-1.5	-1.9	-2.1	-2.1	-1.7
Business marketing and listing	AUD Mio.	-1.1	-1.7	-1.4	-0.8	-0.7	-0.6	-0.8	-0.6
Licenses patents and trademarks	AUD Mio.	-1.0	-1.0	-0.9	-0.9	-0.7	-0.1	-0.1	-0.2
General operations	AUD Mio.	-2.4	-3.6	-7.3	-5.4	-2.8	-4.8	-4.7	-4.4
Other operating income	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.9
in % of total net sales	%	0%	0%	0%	0%	0%	0%	0%	48%
Other expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>EBITDA</b>	<b>AUD Mio.</b>	<b>-8.6</b>	<b>-8.2</b>	<b>-13.8</b>	<b>-14.5</b>	<b>-10.8</b>	<b>-11.3</b>	<b>-9.7</b>	<b>-6.7</b>
in % of total net sales	%	-718%	-319%	-321%	-500%	-585%	-497%	-750%	-344%
YoY	%	-23%	-6%	69%	5%	-26%	5%	-14%	-30%
Depreciation and amortisation	AUD Mio.	-2.1	-1.0	-0.8	-0.9	-0.7	-0.1	-0.1	-0.1
in % of total net sales	%	-178%	-40%	-20%	-29%	-39%	-4%	-5%	-3%
<b>EBIT</b>	<b>AUD Mio.</b>	<b>-10.8</b>	<b>-9.2</b>	<b>-14.7</b>	<b>-15.4</b>	<b>-11.5</b>	<b>-11.4</b>	<b>-9.8</b>	<b>-6.8</b>
in % of total net sales	%	-896%	-359%	-341%	-529%	-624%	-501%	-755%	-
YoY	%	-10%	-15%	60%	5%	-25%	-1%	-14%	-30%
Interest income	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest costs	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>EBT</b>	<b>AUD Mio.</b>	<b>-10.8</b>	<b>-9.2</b>	<b>-14.7</b>	<b>-15.4</b>	<b>-11.5</b>	<b>-11.4</b>	<b>-9.8</b>	<b>-6.8</b>
in % of total net sales	%	-896%	-359%	-341%	-529%	-624%	-501%	-755%	-346%
Income taxes	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other taxes	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
in % of EBT	%	0%	0%	0%	0%	0%	0%	0%	0%
Tax loss carry forward	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net income after taxes</b>	<b>AUD Mio.</b>	<b>-10.8</b>	<b>-9.2</b>	<b>-14.7</b>	<b>-15.4</b>	<b>-11.5</b>	<b>-11.4</b>	<b>-9.8</b>	<b>-6.8</b>
in % of total net sales	%	-896%	-359%	-341%	-529%	-624%	-501%	-755%	-346%
YoY	%	-10%	-15%	60%	5%	-25%	-1%	-14%	-30%
Minorities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income after minorities	USD Mio.	-10.8	-9.2	-14.7	-15.4	-11.5	-11.4	-9.8	-6.8
Number of shares	1.000	160.5	248.2	302.4	303.2	303.2	30.4	30.8	35.3
<b>Earnings per share (basic)</b>	<b>AUD</b>	<b>-0.07</b>	<b>-0.04</b>	<b>-0.05</b>	<b>-0.05</b>	<b>-0.04</b>	<b>-0.38</b>	<b>-0.32</b>	<b>-0.19</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL



## Profit and loss statement, 2014-21e

		2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>Revenues</b>	<b>AUD Mio.</b>	<b>2.5</b>	<b>3.3</b>	<b>6.4</b>	<b>17.0</b>	<b>46.3</b>	<b>133.4</b>	<b>267.1</b>	<b>409.1</b>
YoY	%	29%	29%	97%	165%	173%	188%	100%	53%
Material expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
in % of total net sales	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Gross profit</b>	<b>AUD Mio.</b>	<b>2.5</b>	<b>3.3</b>	<b>6.4</b>	<b>17.0</b>	<b>46.3</b>	<b>133.4</b>	<b>267.1</b>	<b>409.1</b>
in % of total net sales	%	100%	100%	100%	100%	100%	100%	100%	100%
<b>Expenses</b>	<b>AUD Mio.</b>	<b>-8.5</b>	<b>-14.1</b>	<b>-10.3</b>	<b>-10.0</b>	<b>-24.2</b>	<b>-62.8</b>	<b>-117.5</b>	<b>-169.0</b>
in % of total net sales	%	-336%	-433%	-161%	-59%	-52%	-47%	-44%	-41%
Clinical development	AUD Mio.	-0.7	-0.2	-0.1	-0.1	-0.2	-0.2	-0.2	-0.2
Drug formulating R&D	AUD Mio.	-0.6	-0.5	-1.0	-0.9	-2.4	-6.9	-13.9	-21.5
Regulatory and non-clinical	AUD Mio.	-0.3	-0.7	-1.0	-1.0	-1.3	-1.4	-1.7	-1.8
Clinical, regulatory and commercial	AUD Mio.	-1.7	-1.3	-1.6	-2.1	-5.5	-15.2	-29.6	-43.9
Business marketing and listing	AUD Mio.	-0.5	-0.8	-0.8	-0.8	-2.2	-6.2	-12.4	-18.8
Licenses patents and trademarks	AUD Mio.	-0.2	-0.2	-0.3	-0.2	-0.6	-1.7	-3.4	-5.1
General operations	AUD Mio.	-4.5	-10.5	-5.6	-4.9	-12.1	-31.3	-56.4	-77.7
Other operating income	AUD Mio.	0.5	0.5	0.8	0.2	0.5	1.5	3.0	4.6
in % of total net sales	%	18%	14%	12%	1%	1%	1%	1%	1%
Other expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>EBITDA</b>	<b>AUD Mio.</b>	<b>-5.5</b>	<b>-10.4</b>	<b>-3.1</b>	<b>7.2</b>	<b>22.7</b>	<b>72.0</b>	<b>152.6</b>	<b>244.8</b>
in % of total net sales	%	-217%	-319%	-49%	42%	49%	54%	57%	60%
YoY	%	-19%	89%	-70%	-329%	216%	218%	112%	60%
Depreciation and amortisation	AUD Mio.	0.0	0.0	0.0	-0.1	-0.1	-0.4	-0.8	-1.3
in % of total net sales	%	-1%	-1%	0%	0%	0%	0%	0%	0%
<b>EBIT</b>	<b>AUD Mio.</b>	<b>-5.5</b>	<b>-10.4</b>	<b>-3.2</b>	<b>7.1</b>	<b>22.5</b>	<b>71.6</b>	<b>151.7</b>	<b>243.5</b>
in % of total net sales	%	-219%	-319%	-49%	42%	49%	54%	57%	60%
YoY	%	-19%	88%	-70%	-326%	217%	218%	112%	60%
Interest income	AUD Mio.	0.0	0.0	0.0	0.0	0.2	0.4	1.1	2.5
Interest costs	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>EBT</b>	<b>AUD Mio.</b>	<b>-5.5</b>	<b>-10.4</b>	<b>-3.2</b>	<b>7.1</b>	<b>22.8</b>	<b>72.0</b>	<b>152.8</b>	<b>246.0</b>
in % of total net sales	%	-219%	-319%	-49%	42%	49%	54%	57%	60%
Income taxes	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	-73.8
Other taxes	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
in % of EBT	%	0%	0%	0%	0%	0%	0%	0%	-30%
Tax loss carry forward	AUD Mio.	0.0	0.0	129.2	121.1	98.3	26.3	0.0	0.0
<b>Net income after taxes</b>	<b>AUD Mio.</b>	<b>-5.5</b>	<b>-10.4</b>	<b>-3.2</b>	<b>7.1</b>	<b>22.8</b>	<b>72.0</b>	<b>152.8</b>	<b>172.2</b>
in % of total net sales	%	-219%	-319%	-49%	42%	49%	54%	57%	42%
YoY	%	-19%	88%	-70%	-326%	220%	216%	112%	13%
Minorities	AUD Mio.	0.0	0.0	0.0	-0.1	0.0	0.0	0.0	0.0
Net income after minorities	USD Mio.	-5.5	-10.4	-3.1	7.0	22.8	72.0	152.8	172.2
Number of shares	1.000	38.7	43.4	45.3	47.7	47.7	47.7	47.7	47.7
<b>Earnings per share (basic)</b>	<b>AUD</b>	<b>-0.14</b>	<b>-0.24</b>	<b>-0.07</b>	<b>0.15</b>	<b>0.48</b>	<b>1.51</b>	<b>3.20</b>	<b>3.61</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Balance sheet, 2006-13

		2006	2007	2008	2009	2010	2011	2012	2013
<b>ASSETS</b>									
<b>Long-term assets</b>	<b>AUD Mio.</b>	<b>5.2</b>	<b>31.0</b>	<b>26.9</b>	<b>17.1</b>	<b>7.9</b>	<b>5.6</b>	<b>0.6</b>	<b>0.1</b>
Intangible assets	AUD Mio.	2.9	2.2	1.4	0.7	0.0	0.0	0.0	0.0
Property, plant and equipment	AUD Mio.	0.2	0.3	0.4	0.4	0.3	0.2	0.2	0.1
Participations	AUD Mio.	2.0	28.5	25.0	0.0	0.0	5.3	0.5	0.0
Deferred taxes	AUD Mio.	0.0	0.0	0.0	16.0	7.6	0.0	0.0	0.0
Other non-financial assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables to participations	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pre-paid accounts	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Short-term assets</b>	<b>AUD Mio.</b>	<b>11.9</b>	<b>36.8</b>	<b>28.1</b>	<b>24.6</b>	<b>21.6</b>	<b>14.6</b>	<b>15.4</b>	<b>15.7</b>
Inventories	AUD Mio.	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
DIO	d	173.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables and other assets	AUD Mio.	0.2	0.2	0.6	0.2	0.4	1.0	1.0	1.7
DSO	d	69.9	34.0	51.6	26.2	70.8	154.0	280.2	319.6
Receivables from participations	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables from not paid in capital	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other short-term assets	AUD Mio.	2.5	2.7	1.7	2.6	1.8	1.5	1.6	1.4
Cash	AUD Mio.	8.6	33.8	25.8	21.7	19.4	12.2	12.7	12.6
thereof collateralized	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accrued income	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity not covered by assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total assets</b>	<b>AUD Mio.</b>	<b>17.1</b>	<b>67.8</b>	<b>55.0</b>	<b>41.6</b>	<b>29.5</b>	<b>20.2</b>	<b>16.0</b>	<b>15.8</b>
<b>LIABILITIES</b>									
<b>Equity</b>	<b>AUD Mio.</b>	<b>14.0</b>	<b>65.4</b>	<b>51.8</b>	<b>37.1</b>	<b>26.4</b>	<b>16.4</b>	<b>13.6</b>	<b>13.8</b>
Equity ratio	%	82%	96%	94%	89%	90%	81%	85%	88%
Subscribed capital	AUD Mio.	52.7	112.8	113.2	113.2	113.2	113.3	119.3	126.7
Capital reserve	AUD Mio.	1.2	1.6	1.8	2.2	2.2	3.2	1.8	1.3
Retained earnings	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Profit/Loss	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD Mio.	-39.9	-49.1	-63.2	-78.3	-89.0	-100.1	-107.5	-
Not paid in capital	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Special item	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pension reserves	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other reserves	AUD Mio.	0.1	0.1	0.2	0.2	0.3	0.3	0.3	0.5
<b>Total liabilities</b>	<b>AUD Mio.</b>	<b>3.0</b>	<b>2.3</b>	<b>3.0</b>	<b>4.4</b>	<b>2.8</b>	<b>3.4</b>	<b>2.1</b>	<b>1.5</b>
Bonds	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financial liabilities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trade payables	AUD Mio.	3.0	2.3	3.0	4.4	2.8	3.4	2.1	1.5
Days	d	897	326	249	541	547	543	579	266
Other liabilities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Liabilities to minorities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accrued expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total liabilities</b>	<b>AUD Mio.</b>	<b>17.1</b>	<b>67.8</b>	<b>55.0</b>	<b>41.6</b>	<b>29.5</b>	<b>20.2</b>	<b>16.0</b>	<b>15.8</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL

## Balance sheet, 2014-21e

		2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>ASSETS</b>									
<b>Long-term assets</b>	<b>AUD Mio.</b>	<b>0.1</b>	<b>0.1</b>	<b>0.2</b>	<b>0.1</b>	<b>0.4</b>	<b>1.1</b>	<b>2.2</b>	<b>3.3</b>
Intangible assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Property, plant and equipment	AUD Mio.	0.1	0.1	0.2	0.1	0.4	1.1	2.2	3.3
Participations	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Deferred taxes	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other non-financial assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables to participations	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pre-paid accounts	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Short-term assets</b>	<b>AUD Mio.</b>	<b>17.0</b>	<b>13.6</b>	<b>20.0</b>	<b>28.5</b>	<b>56.5</b>	<b>144.0</b>	<b>320.6</b>	<b>518.1</b>
Inventories	AUD Mio.	0.0	0.8	1.1	1.2	3.4	9.8	19.5	29.9
DIO	d	0.0	92.4	60.7	26.3	26.3	26.3	26.3	26.3
Receivables and other assets	AUD Mio.	1.6	2.0	4.8	3.2	8.8	25.4	50.9	78.0
DSO	d	225.9	216.5	270.5	68.7	68.7	68.7	68.7	68.7
Receivables from participations	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Receivables from not paid in capital	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other short-term assets	AUD Mio.	0.8	0.2	0.2	0.2	0.0	0.0	0.0	0.0
Cash	AUD Mio.	14.6	10.6	13.8	23.8	44.2	108.8	250.1	410.1
thereof collateralized	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accrued income	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Equity not covered by assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total assets</b>	<b>AUD Mio.</b>	<b>17.2</b>	<b>13.6</b>	<b>20.1</b>	<b>28.6</b>	<b>56.8</b>	<b>145.0</b>	<b>322.8</b>	<b>521.4</b>
<b>LIABILITIES</b>									
<b>Equity</b>	<b>AUD Mio.</b>	<b>15.4</b>	<b>11.2</b>	<b>17.8</b>	<b>25.4</b>	<b>48.2</b>	<b>120.2</b>	<b>273.0</b>	<b>445.2</b>
Equity ratio	%	90%	82%	89%	89%	85%	83%	85%	85%
Subscribed capital	AUD Mio.	133.6	138.5	146.8	148.4	148.4	148.4	148.4	148.4
Capital reserve	AUD Mio.	1.4	2.7	4.1	2.8	2.8	2.8	2.8	2.8
Retained earnings	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Profit/Loss	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD Mio.	-119.6	-129.9	-133.1	-125.8	-103.1	-31.0	121.8	294.0
Not paid in capital	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD Mio.	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Special item	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pension reserves	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other reserves	AUD Mio.	0.6	0.6	0.7	0.9	2.4	6.8	13.7	20.9
<b>Total liabilities</b>	<b>AUD Mio.</b>	<b>1.1</b>	<b>1.9</b>	<b>1.6</b>	<b>2.3</b>	<b>6.3</b>	<b>18.0</b>	<b>36.1</b>	<b>55.3</b>
Bonds	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Financial liabilities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trade payables	AUD Mio.	1.1	1.9	1.6	2.3	6.3	18.0	36.1	55.3
Days	d	157	205	88	49	49	49	49	49
Other liabilities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Liabilities to minorities	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Accrued expenses	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total liabilities</b>	<b>AUD Mio.</b>	<b>17.2</b>	<b>13.6</b>	<b>20.1</b>	<b>28.6</b>	<b>56.8</b>	<b>145.0</b>	<b>322.8</b>	<b>521.4</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Balance sheet (normalized version), 2006-13

		2006	2007	2008	2009	2010	2011	2012	2013
<b>ASSETS</b>									
<b>Long-term assets</b>	%	<b>30%</b>	<b>46%</b>	<b>49%</b>	<b>41%</b>	<b>27%</b>	<b>28%</b>	<b>4%</b>	<b>1%</b>
Intangible assets	%	17%	3%	3%	2%	0%	0%	0%	0%
Property, plant and equipment	%	1%	0%	1%	1%	1%	1%	1%	1%
Participations	%	12%	42%	46%	0%	0%	26%	3%	0%
Deferred taxes	%	0%	0%	0%	39%	26%	0%	0%	0%
Other non-financial assets	%	0%	0%	0%	0%	0%	0%	0%	0%
Receivables to participations	%	0%	0%	0%	0%	0%	0%	0%	0%
Pre-paid accounts	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Short-term assets</b>	%	<b>70%</b>	<b>54%</b>	<b>51%</b>	<b>59%</b>	<b>73%</b>	<b>72%</b>	<b>96%</b>	<b>99%</b>
Inventories	%	3%	0%	0%	0%	0%	0%	0%	0%
Receivables and other assets	%	1%	0%	1%	1%	1%	5%	6%	11%
Receivables from participations	%	0%	0%	0%	0%	0%	0%	0%	0%
Receivables from not paid in capital	%	0%	0%	0%	0%	0%	0%	0%	0%
Other short-term assets	%	14%	4%	3%	6%	6%	7%	10%	9%
Cash	%	50%	50%	47%	52%	66%	60%	80%	79%
thereof collateralized	%	0%	0%	0%	0%	0%	0%	0%	0%
Accrued income	%	0%	0%	0%	0%	0%	0%	0%	0%
Equity not covered by assets	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Total assets</b>	%	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>LIABILITIES</b>									
<b>Equity</b>	%	<b>82%</b>	<b>96%</b>	<b>94%</b>	<b>89%</b>	<b>90%</b>	<b>81%</b>	<b>85%</b>	<b>88%</b>
Subscribed capital	%	309%	166%	206%	272%	384%	562%	746%	801%
Capital reserve	%	7%	2%	3%	5%	7%	16%	11%	8%
Retained earnings	%	0%	0%	0%	0%	0%	0%	0%	0%
Profit/Loss	%	0%	0%	0%	0%	0%	0%	0%	0%
Minorities	%	-234%	-72%	-115%	-188%	-302%	-497%	-672%	-
Not paid in capital	%	0%	0%	0%	0%	0%	0%	0%	0%
Minorities	%	0%	0%	0%	0%	0%	0%	0%	0%
Special item	%	0%	0%	0%	0%	0%	0%	0%	0%
Pension reserves	%	0%	0%	0%	0%	0%	0%	0%	0%
Other reserves	%	1%	0%	0%	0%	1%	2%	2%	3%
<b>Total liabilities</b>	%	<b>18%</b>	<b>3%</b>	<b>5%</b>	<b>10%</b>	<b>9%</b>	<b>17%</b>	<b>13%</b>	<b>9%</b>
Bonds	%	0%	0%	0%	0%	0%	0%	0%	0%
Financial liabilities	%	0%	0%	0%	0%	0%	0%	0%	0%
Trade payables	%	18%	3%	5%	10%	9%	17%	13%	9%
Other liabilities	%	0%	0%	0%	0%	0%	0%	0%	0%
Liabilities to minorities	%	0%	0%	0%	0%	0%	0%	0%	0%
Accrued expenses	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Total liabilities</b>	%	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL

## Balance sheet (normalized version), 2014-21e

		2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>ASSETS</b>									
<b>Long-term assets</b>	%	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>0%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>	<b>1%</b>
Intangible assets	%	0%	0%	0%	0%	0%	0%	0%	0%
Property, plant and equipment	%	1%	1%	1%	0%	1%	1%	1%	1%
Participations	%	0%	0%	0%	0%	0%	0%	0%	0%
Deferred taxes	%	0%	0%	0%	0%	0%	0%	0%	0%
Other non-financial assets	%	0%	0%	0%	0%	0%	0%	0%	0%
Receivables to participations	%	0%	0%	0%	0%	0%	0%	0%	0%
Pre-paid accounts	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Short-term assets</b>	%	<b>99%</b>	<b>99%</b>	<b>99%</b>	<b>100%</b>	<b>99%</b>	<b>99%</b>	<b>99%</b>	<b>99%</b>
Inventories	%	0%	6%	5%	4%	6%	7%	6%	6%
Receivables and other assets	%	9%	14%	24%	11%	16%	18%	16%	15%
Receivables from participations	%	0%	0%	0%	0%	0%	0%	0%	0%
Receivables from not paid in capital	%	0%	0%	0%	0%	0%	0%	0%	0%
Other short-term assets	%	5%	1%	1%	1%	0%	0%	0%	0%
Cash	%	85%	77%	69%	83%	78%	75%	77%	79%
thereof collateralized	%	0%	0%	0%	0%	0%	0%	0%	0%
Accrued income	%	0%	0%	0%	0%	0%	0%	0%	0%
Equity not covered by assets	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Total assets</b>	%	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
<b>LIABILITIES</b>									
<b>Equity</b>	%	<b>90%</b>	<b>82%</b>	<b>89%</b>	<b>89%</b>	<b>85%</b>	<b>83%</b>	<b>85%</b>	<b>85%</b>
Subscribed capital	%	779%	1015%	729%	519%	261%	102%	46%	28%
Capital reserve	%	8%	20%	20%	10%	5%	2%	1%	1%
Retained earnings	%	0%	0%	0%	0%	0%	0%	0%	0%
Profit/Loss	%	0%	0%	0%	0%	0%	0%	0%	0%
Minorities	%	-697%	-952%	-661%	-440%	-182%	-21%	38%	56%
Not paid in capital	%	0%	0%	0%	0%	0%	0%	0%	0%
Minorities	%	0%	0%	0%	0%	0%	0%	0%	0%
Special item	%	0%	0%	0%	0%	0%	0%	0%	0%
Pension reserves	%	0%	0%	0%	0%	0%	0%	0%	0%
Other reserves	%	4%	4%	4%	3%	4%	5%	4%	4%
<b>Total liabilities</b>	%	<b>6%</b>	<b>14%</b>	<b>8%</b>	<b>8%</b>	<b>11%</b>	<b>12%</b>	<b>11%</b>	<b>11%</b>
Bonds	%	0%	0%	0%	0%	0%	0%	0%	0%
Financial liabilities	%	0%	0%	0%	0%	0%	0%	0%	0%
Trade payables	%	6%	14%	8%	8%	11%	12%	11%	11%
Other liabilities	%	0%	0%	0%	0%	0%	0%	0%	0%
Liabilities to minorities	%	0%	0%	0%	0%	0%	0%	0%	0%
Accrued expenses	%	0%	0%	0%	0%	0%	0%	0%	0%
<b>Total liabilities</b>	%	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Cash flow statement, 2006-13

		2006	2007	2008	2009	2010	2011	2012	2013
Net income	AUD Mio.	-10.8	-9.2	-14.7	-15.4	-11.5	-11.4	-9.8	-6.8
Depreciations	AUD Mio.	2.1	1.0	0.8	0.9	0.7	0.1	0.1	0.1
Write-ups on fixed assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Inventory	AUD Mio.	-0.5	0.6	0.0	0.0	0.0	0.0	0.0	0.0
Δ Trade receivables	AUD Mio.	-0.1	0.0	-0.4	0.4	-0.2	-0.6	0.0	-0.7
Δ Other receivables	AUD Mio.	-2.2	-0.2	1.0	-0.9	0.8	0.3	-0.2	0.3
Δ Deferred taxes (assets)	AUD Mio.	0.0	0.0	0.0	-16.0	8.5	7.6	0.0	0.0
Δ Provisions	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Other provisions	AUD Mio.	0.0	0.0	0.1	0.0	0.1	0.0	0.0	0.2
Δ Short term provisions	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Payables	AUD Mio.	0.5	-0.7	0.7	1.4	-1.6	0.6	-1.4	-0.6
Δ Other debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Special item	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Deferred taxes (liabilities)	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Currency adjustments	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	AUD Mio.	-0.5	0.3	5.3	18.7	-8.6	-6.2	1.3	0.7
<b>Operating cash flow</b>	<b>%</b>	<b>-11.4</b>	<b>-8.2</b>	<b>-7.2</b>	<b>-11.0</b>	<b>-11.8</b>	<b>-9.5</b>	<b>-10.0</b>	<b>-6.9</b>
YoY	%	23%	-28%	-12%	53%	7%	-19%	6%	-31%
Disbursements for purchases of fixed assets	AUD Mio.	-2.0	-26.5	3.5	25.0	0.0	-5.3	4.9	0.5
Payments for investments in intangibles	AUD Mio.	1.6	0.8	0.8	0.8	0.6	0.0	0.0	0.0
Payments for investments in tangibles	AUD Mio.	-2.1	-1.1	-0.9	-0.8	-0.7	0.0	0.0	0.0
Other adjustments	AUD Mio.	0.2	0.4	-4.0	-18.5	9.7	7.8	-0.1	0.0
<b>Investing cash flow</b>	<b>AUD Mio.</b>	<b>-2.4</b>	<b>-26.5</b>	<b>-0.7</b>	<b>6.5</b>	<b>9.6</b>	<b>2.5</b>	<b>4.8</b>	<b>0.4</b>
YoY	%	114%	1023%	-97%	-980%	48%	-74%	88%	-91%
<b>Free cash flow</b>	<b>AUD Mio.</b>	<b>-13.8</b>	<b>-34.7</b>	<b>-7.9</b>	<b>-4.5</b>	<b>-2.1</b>	<b>-6.9</b>	<b>-5.2</b>	<b>-6.5</b>
YoY	%	33%	152%	-77%	-44%	-52%	224%	-25%	23%
Δ Share capital	AUD Mio.	17.6	60.1	0.4	0.0	0.0	0.1	6.0	7.4
Δ Capital reserves	AUD Mio.	-0.3	0.5	0.1	0.4	0.0	1.0	-1.4	-0.6
Δ Bank debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Bonds	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Other financial debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Outflow for dividends	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	AUD Mio.	0.3	-0.6	-0.5	-0.3	0.0	-1.2	1.2	-0.5
<b>Financing cash flow</b>	<b>AUD Mio.</b>	<b>17.6</b>	<b>60.0</b>	<b>0.0</b>	<b>0.1</b>	<b>0.0</b>	<b>0.0</b>	<b>5.8</b>	<b>6.3</b>
<b>Change in cash</b>	<b>AUD Mio.</b>	<b>3.8</b>	<b>25.4</b>	<b>-7.9</b>	<b>-4.3</b>	<b>-2.1</b>	<b>-6.9</b>	<b>0.5</b>	<b>-0.2</b>
Currency adjustments	AUD Mio.	0.0	-0.1	-0.2	0.3	-0.2	-0.3	0.0	0.0
Cash at beginning of period	AUD Mio.	4.8	8.6	33.8	25.8	21.7	19.4	12.2	12.7
<b>Cash at end of period</b>	<b>AUD Mio.</b>	<b>8.6</b>	<b>33.8</b>	<b>25.8</b>	<b>21.7</b>	<b>19.4</b>	<b>12.2</b>	<b>12.7</b>	<b>12.6</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL

## Cash flow statement, 2014-21e

		2014	2015	2016	2017	2018e	2019e	2020e	2021e
Net income	AUD Mio.	-5.5	-10.4	-3.2	7.1	22.8	72.0	152.8	172.2
Depreciations	AUD Mio.	0.0	0.0	0.0	0.1	0.1	0.4	0.8	1.3
Write-ups on fixed assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Inventory	AUD Mio.	0.0	-0.8	-0.2	-0.2	-2.1	-6.4	-9.8	-10.4
Δ Trade receivables	AUD Mio.	0.2	-0.4	-2.9	1.6	-5.6	-16.6	-25.5	-27.1
Δ Other receivables	AUD Mio.	0.5	0.6	0.0	0.0	0.2	0.0	0.0	0.0
Δ Deferred taxes (assets)	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Provisions	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Other provisions	AUD Mio.	0.1	0.0	0.2	0.1	1.5	4.5	6.8	7.3
Δ Short term provisions	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Payables	AUD Mio.	-0.3	0.8	-0.3	0.7	4.0	11.8	18.1	19.2
Δ Other debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Special item	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Deferred taxes (liabilities)	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Currency adjustments	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	AUD Mio.	0.2	5.7	1.4	0.5	0.0	0.0	0.0	0.0
<b>Operating cash flow</b>	<b>%</b>	<b>-4.8</b>	<b>-4.5</b>	<b>-5.0</b>	<b>9.9</b>	<b>20.9</b>	<b>65.7</b>	<b>143.3</b>	<b>162.4</b>
YoY	%	-30%	-6%	11%	-297%	110%	215%	118%	13%
Disbursements for purchases of fixed assets	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payments for investments in intangibles	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Payments for investments in tangibles	AUD Mio.	0.0	0.0	-0.1	0.0	-0.4	-1.1	-1.9	-2.4
Other adjustments	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Investing cash flow</b>	<b>AUD Mio.</b>	<b>0.0</b>	<b>0.0</b>	<b>-0.1</b>	<b>-0.1</b>	<b>-0.4</b>	<b>-1.1</b>	<b>-1.9</b>	<b>-2.4</b>
YoY	%	-101%	208%	817%	-31%	468%	193%	71%	27%
<b>Free cash flow</b>	<b>AUD Mio.</b>	<b>-4.8</b>	<b>-4.5</b>	<b>-5.1</b>	<b>9.8</b>	<b>20.5</b>	<b>64.6</b>	<b>141.4</b>	<b>160.0</b>
YoY	%	-25%	-6%	13%	-292%	108%	215%	119%	13%
Δ Share capital	AUD Mio.	6.9	4.9	8.3	1.6	0.0	0.0	0.0	0.0
Δ Capital reserves	AUD Mio.	0.2	1.3	1.4	-1.3	0.0	0.0	0.0	0.0
Δ Bank debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Bonds	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Δ Other financial debt	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Outflow for dividends	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other adjustments	AUD Mio.	-0.2	-5.9	-1.3	-0.3	0.0	-0.1	0.0	0.0
<b>Financing cash flow</b>	<b>AUD Mio.</b>	<b>6.9</b>	<b>0.2</b>	<b>8.4</b>	<b>0.1</b>	<b>0.0</b>	<b>-0.1</b>	<b>0.0</b>	<b>0.0</b>
<b>Change in cash</b>	<b>AUD Mio.</b>	<b>2.1</b>	<b>-4.3</b>	<b>3.3</b>	<b>9.9</b>	<b>20.5</b>	<b>64.5</b>	<b>141.4</b>	<b>160.0</b>
Currency adjustments	AUD Mio.	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0
Cash at beginning of period	AUD Mio.	12.6	14.6	10.6	13.8	23.8	44.2	108.8	250.1
<b>Cash at end of period</b>	<b>AUD Mio.</b>	<b>14.6</b>	<b>10.6</b>	<b>13.8</b>	<b>23.8</b>	<b>44.2</b>	<b>108.8</b>	<b>250.1</b>	<b>410.1</b>

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Segments, 2006-13

		2006	2007	2008	2009	2010	2011	2012	2013
<b>Revenues by region</b>	<b>AUD Mio.</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>1.3</b>	<b>2.0</b>
Europe	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	1.3	2.0
America	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Asia and Australia	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Africa	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>YoY</b>	<b>%</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>52%</b>
Europe	%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	52%
America	%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Asia and Australia	%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Africa	%	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>Share</b>	<b>%</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>n/a</b>	<b>100%</b>	<b>100%</b>
Europe	%	n/a	n/a	n/a	n/a	n/a	n/a	100%	100%
America	%	n/a	n/a	n/a	n/a	n/a	n/a	0%	0%
Asia and Australia	%	n/a	n/a	n/a	n/a	n/a	n/a	0%	0%
Africa	%	n/a	n/a	n/a	n/a	n/a	n/a	0%	0%

SOURCE: COMPANY DATA, SPHENE CAPITAL



## Segments, 2014-21e

		2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>Revenues by region</b>	<b>AUD Mio.</b>	<b>2.5</b>	<b>3.3</b>	<b>6.4</b>	<b>17.0</b>	<b>46.3</b>	<b>133.4</b>	<b>267.1</b>	<b>409.1</b>
Europe	AUD Mio.	2.5	3.3	6.4	16.7	35.6	83.0	143.0	183.4
America	AUD Mio.	0.0	0.0	0.0	0.3	10.8	33.8	90.7	174.1
Asia and Australia	AUD Mio.	0.0	0.0	0.0	0.0	0.0	16.1	32.3	49.4
Africa	AUD Mio.	0.0	0.0	0.0	0.0	0.0	0.4	1.1	2.2
<b>YoY</b>	<b>%</b>	<b>29%</b>	<b>29%</b>	<b>97%</b>	<b>165%</b>	<b>173%</b>	<b>188%</b>	<b>100%</b>	<b>53%</b>
Europe	%	29%	29%	97%	160%	113%	133%	72%	28%
America	%	n/a	n/a	n/a	n/a	3312%	214%	168%	92%
Asia and Australia	%	n/a	n/a	n/a	n/a	n/a	n/a	100%	53%
Africa	%	n/a	n/a	n/a	n/a	n/a	n/a	200%	104%
<b>Share</b>	<b>%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>
Europe	%	100%	100%	100%	98%	77%	62%	54%	45%
America	%	0%	0%	0%	2%	23%	25%	34%	43%
Asia and Australia	%	0%	0%	0%	0%	0%	12%	12%	12%
Africa	%	0%	0%	0%	0%	0%	0%	0%	1%

SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS

## Prevalence, 2018e

	<b>2018e</b>
<b>Prevalence (EPP), worldwide, reported</b>	<b>6,827</b>
<b>Europe</b>	<b>1,926</b>
GER	400
AUT	40
SUI	65
FRA	300
GBR	389
IRE	12
ITA	120
Benelux	241
DEN	135
SWE	51
NOR	47
ESP	26
POR	100
Other territories in Europe	0
<b>America</b>	<b>4,443</b>
USA	4,300
CDN	125
BRZ	18
Other territories in the Americas	0
<b>Asia and Australia</b>	<b>500</b>
JPN	136
AUS	364
Other territories in Australasia	0
<b>Africa</b>	<b>33</b>
RZA	33
Other territories in Africa	0
SOURCE: SPHENE CAPITAL	

## Clinuvel’s number of EPP patients, 2017-21e

	2014	2015	2016	2017	2018e	2019e	2020e	2021e
<b>Number of patients, worldwide</b>	n/a	n/a	n/a	265	428	1,237	2,479	3,724
<b>Europe</b>	n/a	n/a	n/a	260	328	769	1,326	1,668
GER	n/a	n/a	n/a	45	120	240	360	363
AUT	n/a	n/a	n/a	10	12	24	36	36
SUI	n/a	n/a	n/a	60	6	19	39	58
FRA	n/a	n/a	n/a	0	30	90	180	270
GBR	n/a	n/a	n/a	0	38	116	233	350
IRE	n/a	n/a	n/a	0	1	3	7	10
ITA	n/a	n/a	n/a	25	36	72	108	109
Benelux	n/a	n/a	n/a	120	72	144	216	218
DEN	n/a	n/a	n/a	0	13	40	81	121
SWE	n/a	n/a	n/a	0	0	5	15	30
NOR	n/a	n/a	n/a	0	0	4	14	28
ESP	n/a	n/a	n/a	0	0	2	7	15
POR	n/a	n/a	n/a	0	0	10	30	60
Other territories in Europe	n/a	n/a	n/a	0	0	0	0	0
<b>America</b>	n/a	n/a	n/a	5	100	314	843	1,586
USA	n/a	n/a	n/a	5	100	300	800	1,500
CDN	n/a	n/a	n/a	0	0	13	38	75
BRZ	n/a	n/a	n/a	0	0	2	5	11
Other territories in the Americas	n/a	n/a	n/a	0	0	0	0	0
<b>Asia and Australia</b>	n/a	n/a	n/a	0	0	150	300	450
JPN	n/a	n/a	n/a	0	0	41	81	122
AUS	n/a	n/a	n/a	0	0	109	219	328
Other territories in Australasia	n/a	n/a	n/a	0	0	0	0	0
<b>Africa</b>	n/a	n/a	n/a	0	0	3	10	20
RZA	n/a	n/a	n/a	0	0	3	10	20
Other territories in Africa	n/a	n/a	n/a	0	0	0	0	0

SOURCE: SPHENE CAPITAL FORECASTS

## One view I, 2008-14

		2008	2009	2010	2011	2012	2013	2014
<b>Key data</b>								
Revenues	AUD mn	4.3	2.9	1.8	2.3	1.3	2.0	2.5
Gross profit	AUD mn	4.3	2.9	1.8	2.3	1.3	2.0	2.5
EBITDA	AUD mn	-13.8	-14.5	-10.8	-11.3	-9.7	-6.7	-5.5
EBIT	AUD mn	-14.7	-15.4	-11.5	-11.4	-9.8	-6.8	-5.5
EBT	AUD mn	-14.7	-15.4	-11.5	-11.4	-9.8	-6.8	-5.5
Net income	AUD mn	-14.7	-15.4	-11.5	-11.4	-9.8	-6.8	-5.5
Nr. of employees		n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>Per share data</b>								
Price high	AUD	9.00	4.00	3.65	2.55	2.30	2.73	2.10
Price low	AUD	3.00	1.85	2.15	1.63	1.41	1.50	0.92
Price average	AUD	4.72	2.68	2.80	2.03	1.68	1.92	1.57
Price average/last	AUD	3.10	2.80	2.25	1.66	1.59	1.97	1.70
EPS	AUD	-0.05	-0.05	-0.04	-0.38	-0.32	-0.19	-0.14
BVPS	AUD	0.17	0.12	0.09	0.54	0.44	0.39	0.40
CFPS	AUD	-0.02	-0.04	-0.04	-0.31	-0.33	-0.20	-0.12
Dividend	AUD	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Price target	AUD							
Performance to price target	%							
<b>Profitability ratios (based on revenues)</b>								
EBITDA margin	%	-321%	-500%	-585%	-497%	-750%	-344%	-217%
EBIT margin	%	-341%	-529%	-624%	-501%	-755%	-346%	-219%
Pre-tax margin	%	-341%	-529%	-624%	-501%	-755%	-346%	-219%
Net margin	%	-341%	-529%	-624%	-501%	-755%	-346%	-219%
FCF margin	%	0%	0%	0%	0%	0%	0%	0%
ROE	%	-28%	-41%	-44%	-70%	-72%	-49%	-36%
NWC/Sales	%	-55%	-143%	-132%	-108%	-83%	15%	19%
Revenues per head	AUD	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EBIT per head	AUD	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Capex/Sales	%	-22%	-27%	-37%	1%	-2%	-1%	0%
<b>Growth ratios</b>								
Revenues	%	68%	-32%	-36%	23%	-43%	52%	29%
Gross profit	%	68%	-32%	-36%	23%	-43%	52%	29%
EBITDA	%	69%	5%	-26%	5%	-14%	-30%	-19%
EBIT	%	60%	5%	-25%	-1%	-14%	-30%	-19%
EBT	%	60%	5%	-25%	-1%	-14%	-30%	-19%
Net income	%	60%	5%	-25%	-1%	-14%	-30%	-19%
EPS	%	31%	5%	-25%	889%	-15%	-39%	-26%
CFPS	%	-28%	53%	7%	704%	4%	-40%	-36%
SOURCE: COMPANY DATA, SPHENE CAPITAL								

## One view I, 2015-21e

		2015	2016	2017	2018e	2019e	2020e	2021e
<b>Key data</b>								
Revenues	AUD mn	3.3	6.4	17.0	46.3	133.4	267.1	409.1
Gross profit	AUD mn	3.3	6.4	17.0	46.3	133.4	267.1	409.1
EBITDA	AUD mn	-10.4	-3.1	7.2	22.7	72.0	152.6	244.8
EBIT	AUD mn	-10.4	-3.2	7.1	22.5	71.6	151.7	243.5
EBT	AUD mn	-10.4	-3.2	7.1	22.8	72.0	152.8	246.0
Net income	AUD mn	-10.4	-3.2	7.1	22.8	72.0	152.8	172.2
Nr. of employees		n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>Per share data</b>								
Price high	AUD	5.10	5.00	9.19	9.16			
Price low	AUD	1.30	2.50	4.10	6.13			
Price average	AUD	3.27	3.30	6.65	7.38			
Price last	AUD	2.84	4.32	6.98	8.65	8.65	8.65	8.65
EPS	AUD	-0.24	-0.07	0.15	0.48	1.51	3.20	3.61
BVPS	AUD	0.26	0.39	0.53	1.01	2.52	5.72	9.33
CFPS	AUD	-0.10	-0.11	0.21	0.44	1.38	3.00	3.40
Dividend	AUD	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Price target	AUD							31.70
Performance to price target	%							266.5%
<b>Profitability ratios (based on revenues)</b>								
EBITDA margin	%	-319%	-49%	42%	49%	54%	57%	60%
EBIT margin	%	-319%	-49%	42%	49%	54%	57%	60%
Pre-tax margin	%	-319%	-49%	42%	49%	54%	57%	60%
Net margin	%	-319%	-49%	42%	49%	54%	57%	42%
FCF margin	%	-139%	-80%	58%	44%	48%	53%	39%
ROE	%	-93%	-18%	28%	47%	60%	56%	39%
NWC/Sales	%	29%	67%	13%	13%	13%	13%	13%
Revenues per head	AUD	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EBIT per head	AUD	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Capex/Sales	%	1%	-2%	0%	-1%	-1%	-1%	-1%
<b>Growth ratios</b>								
Revenues	%	29%	97%	165%	173%	188%	100%	53%
Gross profit	%	29%	97%	165%	173%	188%	100%	53%
EBITDA	%	89%	-70%	-329%	216%	218%	112%	60%
EBIT	%	88%	-70%	-326%	217%	218%	112%	60%
EBT	%	88%	-70%	-326%	220%	216%	112%	61%
Net income	%	88%	-70%	-326%	220%	216%	112%	13%
EPS	%	68%	-71%	-315%	223%	216%	112%	13%
CFPS	%	-16%	6%	-287%	110%	215%	118%	13%
SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS								

## One view II, 2008-14

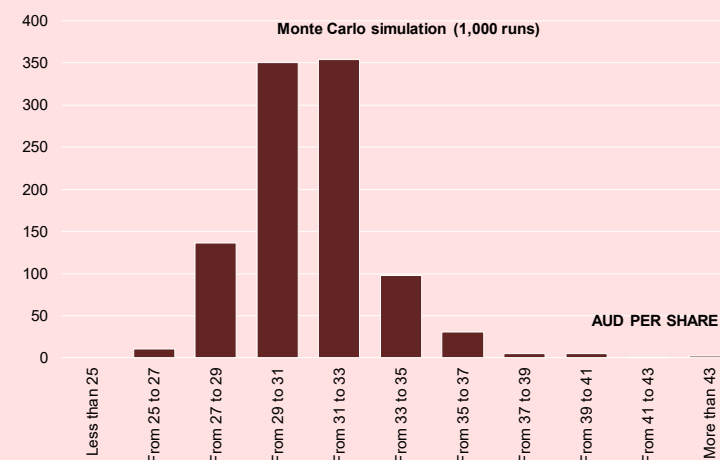
		2008	2009	2010	2011	2012	2013	2014
<b>Balance sheet ratios</b>								
Fixed assets	AUD mn	26.9	17.1	7.9	5.6	0.6	0.1	0.1
Financial assets	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Current assets	AUD mn	28.1	24.6	21.6	14.6	15.4	15.7	17.0
Equity	AUD mn	51.8	37.1	26.4	16.4	13.6	13.8	15.4
Liabilities	AUD mn	3.0	4.4	2.8	3.4	2.1	1.5	1.1
Equity ratio	%	94.3%	89.0%	89.6%	81.4%	85.3%	87.5%	89.9%
Gearing	%	-49.7%	-58.6%	-73.5%	-74.2%	-93.3%	-90.8%	-94.8%
Working Capital	AUD mn	-2.4	-4.2	-2.4	-2.5	-1.1	0.3	0.5
Asset Turnover	x	0.1	0.1	0.1	0.1	0.1	0.1	0.1
EBITDA-ICR	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>Enterprise Value</b>								
Nr. of shares	1,000	302.4	303.2	303.2	30.4	30.8	35.3	38.7
Market cap. high	AUD mn	2,721.4	1,212.7	1,106.5	77.4	70.7	96.4	81.3
Market cap. low	AUD mn	907.1	560.9	651.8	49.5	43.4	52.9	35.6
Market cap. average	AUD mn	1,427.2	812.5	848.9	61.6	51.7	67.8	60.8
Market cap. last	AUD mn	937.4	848.9	682.1	50.4	48.9	69.5	65.8
Net debt	AUD mn	-25.8	-21.7	-19.4	-12.2	-12.7	-12.6	-14.6
Pension reserves	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Non-operating financial assets	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Enterprise Value high	AUD mn	2,695.7	1,190.9	1,087.1	65.2	58.0	83.8	66.6
Enterprise Value low	AUD mn	881.4	539.1	632.4	37.3	30.7	40.4	21.0
Enterprise Value average	AUD mn	1,401.5	790.8	829.4	49.5	39.0	55.2	46.1
Enterprise Value last	AUD mn	911.6	827.1	662.7	38.2	36.2	57.0	51.2
<b>Valuation ratios</b>								
EV/sales high	x	627.32	409.98	589.00	28.67	44.84	42.67	26.38
EV/sales low	x	205.11	185.60	342.62	16.39	23.69	20.56	8.30
EV/sales average	x	326.15	272.22	449.39	21.73	30.11	28.11	18.26
EV/sales last	x	212.15	284.74	359.05	16.79	27.97	29.01	20.25
EV/EBITDA high	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBITDA low	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBITDA average	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBITDA last	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBIT high	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBIT low	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBIT average	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
EV/EBIT last	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
P/E high	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
P/E low	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
P/E average	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
P/E last	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
P/BV last	x	18.1	22.9	25.8	3.1	3.6	5.0	4.3
FCF yield	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Dividend-yield	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Cash flow</b>								
Cash flow from Operations	AUD mn	-7.2	-11.0	-11.8	-9.5	-10.0	-6.9	-4.8
Cash flow from Investments	AUD mn	-0.7	6.5	9.6	2.5	4.8	0.4	0.0
Free Cash flow	AUD mn	-7.9	-4.5	-2.1	-6.9	-5.2	-6.5	-4.8
Cash flow from Financing	AUD mn	0.0	0.1	0.0	0.0	5.8	6.3	6.9
SOURCE: COMPANY DATA, SPHENE CAPITAL								

## One view II, 2015-21e

		2015	2016	2017	2018e	2019e	2020e	2021e
<b>Balance sheet ratios</b>								
Fixed assets	AUD mn	0.1	0.2	0.1	0.4	1.1	2.2	3.3
Financial assets	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Current assets	AUD mn	13.6	20.0	28.5	56.5	144.0	320.6	518.1
Equity	AUD mn	11.2	17.8	25.4	48.2	120.2	273.0	445.2
Liabilities	AUD mn	1.9	1.6	2.3	6.3	18.0	36.1	55.3
Equity ratio	%	82.1%	88.6%	88.9%	84.8%	82.9%	84.6%	85.4%
Gearing	%	-94.4%	-77.6%	-93.4%	-91.9%	-90.5%	-91.6%	-92.1%
Working Capital	AUD mn	0.9	4.3	2.2	6.0	17.2	34.4	52.7
Asset Turnover	x	0.2	0.3	0.6	0.8	0.9	0.8	0.8
EBITDA-ICR	x	n/a	n/a	n/a	n/a	n/a	n/a	n/a
<b>Enterprise Value</b>								
Nr. of shares	1,000	43.4	45.3	47.7	47.7	47.7	47.7	47.7
Market cap. high	AUD mn	221.2	226.4	438.1	437.3			
Market cap. low	AUD mn	56.4	113.2	195.4	292.6			
Market cap. average	AUD mn	141.8	149.4	317.0	352.3			
Market cap. last	AUD mn	123.2	195.6	332.7	412.9	412.9	412.9	412.9
Net debt	AUD mn	-10.6	-13.8	-23.8	-44.2	-108.8	-250.1	-410.1
Pension reserves	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minorities	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Non-operating financial assets	AUD mn	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Enterprise Value high	AUD mn	210.6	212.6	414.3	393.0			
Enterprise Value low	AUD mn	45.8	99.4	171.7	248.4			
Enterprise Value average	AUD mn	131.3	135.6	293.3	308.0			
Enterprise Value last	AUD mn	112.6	181.8	309.0	368.7	304.1	162.8	2.8
<b>Valuation ratios</b>								
EV/sales high	x	64.61	33.11	24.39	8.48			
EV/sales low	x	14.05	15.48	10.11	5.36			
EV/sales average	x	40.26	21.12	17.27	6.65			
EV/sales last	x	34.54	28.32	18.19	7.96	2.28	0.61	0.01
EV/EBITDA high	x	n/a	n/a	57.8	17.3			
EV/EBITDA low	x	n/a	n/a	24.0	11.0			
EV/EBITDA average	x	n/a	n/a	40.9	13.6			
EV/EBITDA last	x	n/a	n/a	43.1	16.3	4.2	1.1	0.0
EV/EBIT high	x	n/a	n/a	58.2	17.4			
EV/EBIT low	x	n/a	n/a	24.1	11.0			
EV/EBIT average	x	n/a	n/a	41.2	13.7			
EV/EBIT last	x	n/a	n/a	43.4	16.4	4.2	1.1	0.0
P/E high	x	n/a	n/a	62.2	19.2			
P/E low	x	n/a	n/a	27.7	12.9			
P/E average	x	n/a	n/a	45.0	15.5			
P/E last	x	n/a	n/a	47.2	18.1	5.7	2.7	2.4
P/BV last	x	11.0	11.0	13.1	8.6	3.4	1.5	0.9
FCF yield	%	-3.7%	-2.6%	3.0%	5.0%	15.6%	34.2%	38.8%
Dividend-yield	%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
<b>Cash flow</b>								
Cash flow from Operations	AUD mn	-4.5	-5.0	9.9	20.9	65.7	143.3	162.4
Cash flow from Investments	AUD mn	0.0	-0.1	-0.1	-0.4	-1.1	-1.9	-2.4
Free Cash flow	AUD mn	-4.5	-5.1	9.8	20.5	64.6	141.4	160.0
Cash flow from Financing	AUD mn	0.2	8.4	0.1	0.0	-0.1	0.0	0.0
SOURCE: COMPANY DATA, SPHENE CAPITAL FORECASTS								

## DCF model

		2018e	2019e	2020e	2021e	2022e	2023e	2024e	2025e	2026e	2027e	2028e	2029e	2030e	2031e	2032e	TY	
<b>Revenues</b>	<b>AUD mn</b>	<b>46.3</b>	<b>133.4</b>	<b>267.1</b>	<b>409.1</b>	<b>548.1</b>	<b>566.2</b>	<b>573.7</b>	<b>586.3</b>	<b>601.6</b>	<b>618.1</b>	<b>635.4</b>	<b>653.2</b>	<b>671.5</b>	<b>690.3</b>	<b>709.6</b>	<b>729.5</b>	
YoY	%	172.8%	187.8%	100.3%	53.2%	34.0%	3.3%	1.3%	2.2%	2.6%	2.7%	2.8%	2.8%	2.8%	2.8%	2.8%	2.8%	
<b>EBIT</b>	<b>AUD mn</b>	<b>22.5</b>	<b>71.6</b>	<b>151.7</b>	<b>243.5</b>	<b>338.7</b>	<b>351.8</b>	<b>357.9</b>	<b>357.6</b>	<b>358.5</b>	<b>359.7</b>	<b>360.8</b>	<b>361.8</b>	<b>362.5</b>	<b>363.0</b>	<b>363.2</b>	<b>368.4</b>	
EBIT margin	%	48.6%	53.7%	56.8%	59.5%	61.8%	62.1%	62.4%	61.0%	59.6%	58.2%	56.8%	55.4%	54.0%	52.6%	51.2%	50.5%	
Taxes	AUD mn	0.0	0.0	0.0	-73.8	-102.8	-107.5	-110.0	-109.9	-110.2	-110.6	-110.9	-111.2	-111.5	-111.6	-111.7	-113.3	
Tax rate (τ)	%	0.0%	0.0%	0.0%	30.3%	30.4%	30.5%	30.7%	30.7%	30.7%	30.7%	30.7%	30.7%	30.7%	30.7%	30.7%	30.7%	
<b>EBIT(1-τ)</b>	<b>AUD mn</b>	<b>22.5</b>	<b>71.6</b>	<b>151.7</b>	<b>169.7</b>	<b>235.8</b>	<b>244.4</b>	<b>247.9</b>	<b>247.7</b>	<b>248.3</b>	<b>249.1</b>	<b>249.9</b>	<b>250.6</b>	<b>251.1</b>	<b>251.4</b>	<b>251.6</b>	<b>255.1</b>	
Investments (Capex, M&A, WC)	AUD mn	-4.2	-12.3	-19.1	-20.7	-27.4	-4.7	-2.4	-4.8	-6.1	-6.8	-7.2	-7.4	-7.6	-7.8	-8.1	-6.6	
<b>FCFF</b>	<b>AUD mn</b>	<b>18.4</b>	<b>59.3</b>	<b>132.6</b>	<b>149.0</b>	<b>208.5</b>	<b>239.6</b>	<b>245.4</b>	<b>242.9</b>	<b>242.1</b>	<b>242.3</b>	<b>242.7</b>	<b>243.2</b>	<b>243.4</b>	<b>243.6</b>	<b>243.5</b>	<b>248.5</b>	
WACC	%	14.1%	14.1%	14.1%	14.5%	14.5%	14.5%	14.5%	13.6%	12.8%	12.0%	11.1%	10.3%	9.5%	8.6%	7.8%		
Discount rate	%	100.0%	87.7%	76.9%	67.1%	58.7%	51.2%	44.8%	39.4%	34.9%	31.2%	28.1%	25.4%	23.2%	21.4%	19.9%		
<b>PV(FCFF)</b>	<b>AUD mn</b>	<b>18.4</b>	<b>52.0</b>	<b>101.9</b>	<b>100.0</b>	<b>122.3</b>	<b>122.8</b>	<b>109.9</b>	<b>95.7</b>	<b>84.6</b>	<b>75.6</b>	<b>68.1</b>	<b>61.9</b>	<b>56.6</b>	<b>52.1</b>	<b>48.3</b>		
Terminal cash flow	AUD mn																248.5	
Terminal Cost of capital	%																	7.8%
Terminal value	AUD mn																	1,615.5
Present value of Terminal value	AUD mn																	320.7
in % of Enterprise Value	%																	21.5%
PV FCFF during detailed planning phase	AUD mn																	272.3
in % of Enterprise Value	%																	18.3%
PV FCFF during rough planning phase	AUD mn																	897.8
in % of Enterprise Value	%																	60.2%
<b>Enterprise Value</b>	<b>AUD mn</b>																	<b>1,490.8</b>
Financial debt	AUD mn																	0.0
Excess cash	AUD mn																	23.8
<b>Value of equity</b>	<b>AUD mn</b>																	<b>1,514.5</b>
Number of shares	mn																	47.7
<b>Estimated value per share</b>	<b>AUD</b>																	<b>31.70</b>



SOURCE: SPHENE CAPITAL FORECASTS



This publication is issued by



Beim Kraftwerk 8 – 82065 Baierbrunn - Germany - Phone +49 (89) 7444 3558 Fax +49 (89) 7444 3445

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Very high	>80%
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Medium	20-50%
Low	<20%

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<b>Date/Time of publication:</b>	<b>Price target/Current share price:</b>	<b>Rating/Validity:</b>	<b>Conflict of Interest (key)</b>
30 01 2018/09:30 h	AUD 31.70/AUD 8.65	Buy, 12 months	-

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