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Clinuvel Pharmaceuticals (CUV)

Looking to Vitiligo

Recommendation
Buy (unchanged)
Price
$14.60
Target (12 months)
$22.25 (unchanged)

Sector

Pharmaceuticals & Biotechnology

Expected Return	
Capital growth	**52.4%**
Dividend yield	**0.3%**
Total expected return	**52.7%**

Company Data & Ratios	
Enterprise value	**$567.0m**
Market cap	**$741.5m**
Issued capital	**50.1m**
Free float	**89.2%**
Avg. daily val. (52wk)	**$1.6m**
12 month price range	**$12.96 - $21.45**

Price Performance

	(1m)	(3m)	(12m)
Price (A$)	15.62	13.32	18.95
Absolute (%)	-6.66	9.46	-23.06
Rel market (%)	-6.19	9.81	-30.78

Reviewing vitiligo expectations, Phase 3 readout CY25

CUV are conducting two Phase 3 trials to expand the label of Scenesse to include patients with vitiligo. Following recent company announcements, we have revisited vitiligo development expectations and market forecasts. The first Phase 3 trial primary readout is expected in 2H CY25 and represents one of the next major catalysts for the company excluding financial results. Assuming the Phase 3 trials proceed smoothly, we expect submission to the FDA in late CY26 for potential approval by end-CY27.

With ~1% of the US population affected by vitiligo, the market size is far greater than the single rare disease for which Scenesse is currently approved. We estimate a directly addressable vitiligo market in the US of ~65-70k patients (vs. ~2k patients for EPP). This translates into legitimate potential for Scenesse to increase its annual sales several fold if the Phase 3 trials succeed and regulatory approval is granted.

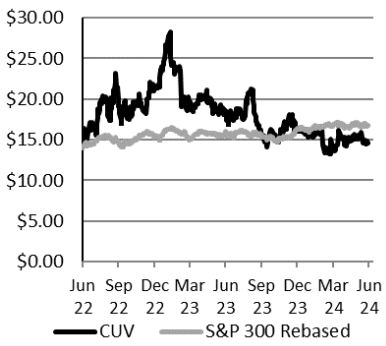
Generic drug for ACTH also progressing

Beyond vitiligo, CUV are pursuing Scenesse label expansion in other rare diseases (e.g. xeroderma pigmentosum and variegate porphyria) with smaller market opportunities. We also have a positive view on CUV's development of an ACTH generic, a peptide closely related to Scenesse and expected to be submitted to the FDA in CY26. Only two ACTH products are on the market currently with combined annual sales of ~US$600m.

Investment view: Maintain BUY and $22.25 PT

Our near-term forecasts remain unchanged and are based on ongoing sales in EPP, where CUV is expected to maintain a commercial monopoly for at least another 3-4 years. There is no change to our BUY recommendation and $22.25 PT. Our valuation is based on a DCF (10.0% WACC, 2.0% TGR) and EV/EBITDA multiple (17.5x). We view the first vitiligo Phase 3 readout in CY25 as a significant catalyst for the company and see the current CUV price as a good entry point for those willing to take on clinical risk with downside mitigated to a degree by the existing, profitable EPP franchise.

Absolute Price



SOURCE: IRESS

Earnings Forecast

June Year End	FY23	FY24e	FY25e	FY26e
Revenue (A$m)	78.3	86.0	93.2	103.1
EBITDA (A$m)	42.5	44.2	48.0	54.2
NPAT (pre abnormals) (A$m)	30.6	35.0	36.3	37.1
Diluted EPS (cps)	59.1	69.9	72.4	74.0
EPS growth (%)	47%	14%	4%	2%
PE (x)	24.7	20.9	20.2	19.7
EV/EBITDA (x)	13.4	12.8	11.8	10.5
FCF yield (%)	6.2%	6.2%	6.1%	6.3%
Dividend (cps)	5.0	5.0	5.0	5.0
Franking (%)	100.0%	100.0%	100.0%	100.0%
Dividend yield (%)	0.3%	0.3%	0.3%	0.3%
ROE (%)	18.6%	17.8%	15.7%	14.0%

SOURCE: BELL POTTER SECURITIES ESTIMATES

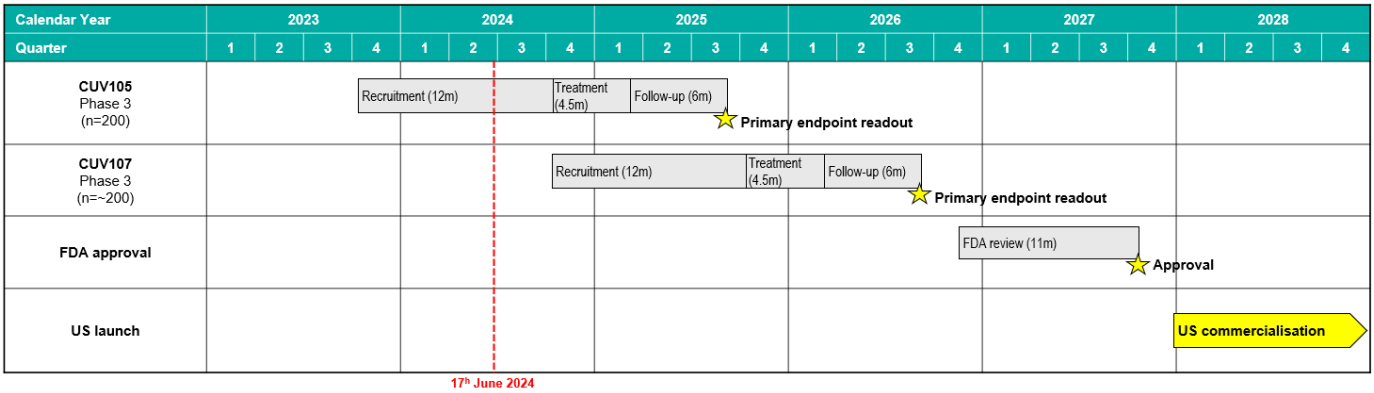
Vitiligo Expectations

First Phase 3 readout expected in 2H CY25

Clinuvel are currently conducting one, and soon to be two, Phase 3 clinical trials to achieve label expansion of Scenesse (afamelanotide) for patients with vitiligo.

Following recent updates from the company, we have reviewed our expectations for clinical and regulatory timings, as well as initial market forecasts. Our estimated timeline to approval and launch is shown in Figure 1 below.

Figure 1 - Estimated Development Timeline for Scenesse Vitiligo Label Expansion



SOURCE: BELL POTTER SECURITIES ESTIMATES

We expect the primary readout for the first Phase 3 trial (called CUV105) in ~**2H CY25**, assuming all 200 subjects are recruited by October 2024 as guided. Primary endpoint is a measurement called T-VASI50, the percentage of patients who have a 50% improvement in their total-body vitiligo measure from baseline.

The second Phase 3 trial (called CUV107) has not yet commenced but should read out roughly ~12 months after CUV105 (i.e., in **~2H CY26**), assuming enrolment commences before the end of CY24 as guided.

We therefore anticipate a label expansion application could be submitted to the FDA towards the end of CY26 for potential **approval in 2H CY27**. First US sales therefore forecast from FY28.

Reviewing US vitiligo forecasts

We have limited our vitiligo forecasts solely to the US market. While further details from the Phase 3 readouts, final label, and pricing will refine our forecasts, we describe current expectations below.

- US market launch in FY28.
- Eligible treatment population of ~65-70k vitiligo patients with darker complexions (Fitzpatrick IV-VI), affected body surface area >10%, and actively seeking treatment[1].
- Note that in vitiligo, and unlike in EPP, patients will receive Scenesse every 3 weeks **for a limited period of ~5 months only** (7-9 doses). Thereafter, each patient will likely require only 1-2 maintenance doses per year. Hence treatment is much more 'one-off' in nature compared to EPP which has constant annual dosing per patient.
- Price of US$12k per dose = US$96k for first year (assuming 8 doses).

[1] 29% of US vitiligo patients have Fitzpatrick IV-VI, and 29% of patients have affected BSA >10% (link). Assumed 30% actively seeking treatment. Source: Bibeau et al., (2022), Presentation 34630 at the American Academy of Dermatology Annual Meeting.

Figure 2 - Scenesse Vitiligo US Forecast

	Historical									Forecast												
Financial Year	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY24e	FY25e	FY26e	FY27e	FY28e	FY29e	FY30e	FY31e	FY32e	FY33e	FY34e	FY35e	FY36e
USA																						
Adult population (m)								261	262	264	265	266	268	269	270	272	273	274	276	277	278	280
Vitiligo prevalence (%)								1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%	1.0%
Vitiligo prevalence (m)								2.6	2.6	2.6	2.6	2.7	2.7	2.7	2.7	2.7	2.7	2.7	2.8	2.8	2.8	2.8
Fitzpatrick IV-VI patients								29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%
Surface area >10%								29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%	29%
Addressable vitiligo patients: Fitzpatrick IV-VI, Surface area >10% (millions)								0.22	0.22	0.22	0.22	0.22	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.23	0.24
Seeking treatment (%)								30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%	30%
Eligible Scenesse patient population								**65,850**	**66,180**	**66,510**	**66,843**	**67,177**	**67,513**	**67,851**	**68,190**	**68,531**	**68,874**	**69,218**	**69,564**	**69,912**	**70,261**	**70,613**
New patient starts per year											-	-	-	500	1,000	2,000	2,000	2,000	2,000	2,000	2,000	2,000
Maintenance patients											-	-	-	-	500	1,500	3,500	5,500	7,500	9,500	11,500	13,500
Penetration of eligible population (%)															0.7%	2.2%	5.1%	7.9%	10.8%	13.6%	16.4%	19.1%
Total doses											-	-	-	3,400	7,438	15,513	18,063	20,613	23,163	25,713	28,263	30,813
Price per dose (US$)														12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000	12,000
Sales (unadjusted)										-	-	-	-	**41**	**89**	**186**	**217**	**247**	**278**	**309**	**339**	**370**
Risk adjustment										45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%	45%
Sales (risk-adjusted)										-	-	-	-	**18**	**40**	**84**	**98**	**111**	**125**	**139**	**153**	**166**

First year doses per patient: 8.0
Annual maintenance doses per patient: 1.5
Compliance: 85%

SOURCE: BELL POTTER SECURITIES ESTIMATES

As per the Figure 2 forecast, we assume:

- 2k new patients per year starting treatment, after 3-year ramp up. This translates to 8% of the ~65-70k eligible patients receiving treatment by FY32 and ~19% by FY36.
- Annual sales (unadjusted) of **US$186m in FY30, increasing to ~US$250m by FY32**.
- Probability of success currently 45%.

Phase 3 readout the clear catalyst

A major de-risking event will be the first Phase 3 read out, expected **in 2H CY25**. While still ~12+ months away, we think a good buying opportunity exists ahead of the readout for those willing to take on a degree of clinical risk.

Further details on historical Phase 2 data for Scenesse in vitiligo, as well as competitive landscape dynamics, are covered in our initiation report (dated 4th October 2023).

Near-term forecasts and $22.25 PT remain unchanged

Our near-term forecasts, built on the existing EPP franchise, remain unchanged. CUV are expected to maintain their commercial monopoly in EPP for at least another 3-4 years, and potentially longer if competitors from Disc Medicine and Mitsubishi Tanabe continue experiencing clinical development difficulties.

Looking to the FY24 result, our $86m revenue forecast remains unchanged, reflecting the same 10% growth rate in 2H24 as 1H24. This compares to the 19% growth in each of the FY23 halves. CUV does not provide any guidance and we are ~$4m below VA consensus revenue of $90.2m.

Figure 3 - Changes to Valuation

	Old		New	
Valuation Methodology	**A$/share**	**Weighting (%)**	**A$/share**	**Weighting (%)**
DCF	23.8	75%	23.3	75%
EV/EBITDA	17.5	25%	18.9	25%
Final valuation	**22.25**	100%	**22.25**	100%

SOURCE: BELL POTTER SECURITIES ESTIMATES

Our DCF is modestly decreased by the above changes to longer-term vitiligo forecasts. We increase our EV/EBITDA multiple to 17.5x, in line with the average of 20 global biopharma peers. As a result, our $22.25 PT remains unchanged and we maintain our BUY recommendation.

Clinuvel Pharmaceuticals (CUV)

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

Company risks include but are not limited to:

- **Competitor risk**: While there are no alternative treatment options currently approved for EPP patients, there are two other companies undergoing clinical trials in EPP for their respective drug candidates. Competitor approval remains uncertain, however, if alternative EPP treatments do end up achieving approval and commercial availability, they would compete for market share of EPP patients with Scenesse.
- **Clinical risk**: Clinuvel is conducting multiple clinical trials to expand the use of afamelanotide in vitiligo, XP, VP and stroke. While initial clinical trials in relatively small subject numbers have been conducted, there is no assurance that ongoing and future clinical trials will achieve efficacy and safety endpoints.
- **Regulatory risk**: The commercialisation of Scenesse in additional indications, as well as the commercialisation of additional pharmaceutical drugs, requires regulatory approval from agencies such as the FDA and EMA. Failure to satisfy regulatory agency requirements regarding clinical, CMC and other data would inhibit the ability of Clinuvel commercialise these drugs in the respective patient populations.
- **Commercial execution risk**: Clinuvel to date has directly commercialised its lead drug for patients with a single rare disease numbering ~5,000-10,000 patients. If Clinuvel are to directly commercialise pharmaceutical products in other disease settings, such as vitiligo and stroke, where there are far greater patient populations and different prescribing channels, we expect an expansion of infrastructure and personnel would be required.
- **Loss of exclusivity**: Due to granted patents and regulatory exclusivity periods, Clinuvel has commercial exclusivity for drugs containing afamelanotide. While it is uncertain if and when any competitors will develop generic afamelanotide products, we estimate generic entry would not be possible before ~FY28 in Europe and ~FY30 in the US, and possibly later if vitiligo becomes an approved indication. Competition from generics could impact sales through pricing pressure and market share of Scenesse.
- **Financial risk:** Clinuvel has been profitable for seven consecutive financial years and thereby generated a cash balance of A$174 million as of 31 December 2023 with no debt. We view Clinuvel as sufficiently financed to continue R&D activities for afamelanotide and other product candidates in the near-term. The company has publicly disclosed on several occasions the goal to internalise manufacturing capabilities and potentially in-license/acquire external pharmaceutical products. Clinuvel has significant cash at hand to execute this strategy and we have not included external funding in our forecasts.

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

Clinuvel Pharmaceuticals

as at 17 June 2024

Recommendation	Buy
Price	$14.60
Target (12 months)	$22.25

Table 1 - Financial summary

Profit & Loss (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Total sales	**65.7**	**78.3**	**86.0**	**93.2**	**103.1**
Growth (%)	*37%*	*19%*	*10%*	*8%*	*11%*
COGS	-6.8	-4.4	-5.2	-5.6	-6.2
Gross Profit	**59.0**	**73.9**	**80.8**	**87.6**	**96.9**
Gross margin	*90%*	*94%*	*94%*	*94%*	*94%*
Other income	0.8	0.8	0.0	0.0	0.0
Operating expenses	-25.2	-32.2	-36.6	-39.5	-42.7
EBITDA	**34.6**	**42.5**	**44.2**	**48.0**	**54.2**
Depreciation & amortisation	-0.8	-0.8	-1.2	-1.2	-1.2
EBIT	**33.9**	**41.7**	**43.0**	**46.8**	**53.0**
EBIT margin	*52%*	*53%*	*50%*	*50%*	*51%*
Net Interest (expense)/benefit	0.4	3.9	7.0	5.0	0.0
Profit before tax	**34.3**	**45.6**	**50.0**	**51.8**	**53.0**
Tax expense	-13.4	-15.0	-15.0	-15.6	-15.9
NPAT (pre abnormals)	**20.9**	**30.6**	**35.0**	**36.3**	**37.1**
Other comprehensive income/(loss)	-1.1	-1.5	0.0	0.0	0.0
Total comprehensive income/(loss)	**19.8**	**29.2**	**35.0**	**36.3**	**37.1**

Valuation Ratios (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Diluted EPS (cents)	40.3	59.1	69.9	72.4	74.0
EPS growth (%)	*-16%*	*47%*	*14%*	*4%*	*2%*
PE(x)	**36.2**	**24.7**	**20.9**	**20.2**	**19.7**
EV/EBITDA (x)	**16.4**	**13.4**	**12.8**	**11.8**	**10.5**
EV/Revenue (x)	8.6	7.2	6.6	6.1	5.5
FCF per share (cents)	92.2	90.8	89.8	89.7	91.7
NTA/share (cents)	291.0	391.7	459.5	529.4	601.4
Price/NTA (x)	5.0	3.7	3.2	2.8	2.4
Book value of equity/share (cents)	254.1	333.2	399.1	467.5	537.6
Price/Book value per share (x)	5.7	4.4	3.7	3.1	2.7
Dividend per share (cents)	4.0	5.0	5.0	5.0	5.0
Dividend payout ratio (%)	9.9%	8.5%	7.2%	6.9%	6.8%
Dividend yield (%)	0.3%	0.3%	0.3%	0.3%	0.3%
Franking (%)	0.0%	100.0%	100.0%	100.0%	100.0%

Cash Flow (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
EBITDA	34.6	42.5	44.2	48.0	54.2
Change in w orking capital	-4.4	0.8	-6.0	1.5	2.1
Gross operating cash flow	**39.0**	**41.6**	**50.3**	**46.5**	**52.1**
Income taxes paid	0.0	-7.7	-15.0	-15.6	-15.9
Net interest income/(payment)	0.2	2.7	7.0	5.0	0.0
Subsidies and grants received	0.6	0.3	0.0	0.0	0.0
Net operating cash flow	**39.9**	**36.9**	**42.2**	**36.0**	**36.2**
Payments for PPE & ROU	-0.4	-1.0	-6.5	-1.0	-1.0
Net investing cash flow	**-0.4**	**-1.0**	**-6.5**	**-1.0**	**-1.0**
Dividends paid	-1.2	-2.0	-2.5	-2.5	-2.5
Payment of lease liabilities	-0.3	-0.3	0.0	0.0	0.0
Net financing cash flow	**-1.5**	**-2.2**	**-2.5**	**-2.5**	**-2.5**
Net change in cash	**37.9**	**33.6**	**33.3**	**32.5**	**32.7**
Cash at start of period	82.7	121.5	156.8	190.1	222.6
Exchange rate impact	**0.9**	**1.7**	**0.0**	**0.0**	**0.0**
Cash at end of period	**121.5**	**156.8**	**190.1**	**222.6**	**255.3**

Performance Ratios	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Gross margin	90%	94%	94%	94%	94%
EBITDA margin	53%	54%	51%	52%	53%
EBIT margin	52%	53%	50%	50%	51%
EBT margin	52%	58%	58%	56%	51%
NPAT margin	32%	39%	41%	39%	36%
Effective tax rate	-39%	-33%	-30%	-30%	-30%

Balance Sheet (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Year Ending 30 June					
Cash and cash equivalents	121.5	156.8	190.1	222.6	255.3
Receivables	16.2	22.2	21.5	23.3	25.8
Inventories	1.8	9.5	5.2	5.6	6.2
Other current assets	1.0	1.1	1.1	1.1	1.1
PPE	1.5	2.0	7.2	6.9	6.6
Right-of-use assets	1.2	0.8	0.9	1.0	1.1
Intangibles	0.2	0.2	0.2	0.2	0.2
Deferred tax assets	0.5	1.1	1.1	1.1	1.1
Total assets	**143.9**	**193.7**	**227.2**	**261.8**	**297.4**
Payables	3.3	7.6	8.6	9.3	10.3
Income tax payables	7.3	16.1	16.1	16.1	16.1
Lease liabilities - current	0.3	0.3	0.3	0.3	0.3
Provisions - current	2.9	1.5	1.5	1.5	1.5
Deferred tax liabilities	3.6	2.8	2.8	2.8	2.8
Lease liabilities - non-current	0.9	0.7	0.7	0.7	0.7
Provisions - non-current	0.1	0.1	0.1	0.1	0.1
Total Liabilities	**18.4**	**29.1**	**30.0**	**30.8**	**31.7**
Net Assets	**125.6**	**164.6**	**197.2**	**231.0**	**265.6**
Issued capital	151.8	151.8	151.8	151.8	151.8
Reserves	12.1	22.6	22.6	22.6	22.6
Retained earnings/(accumulated losses)	-38.4	-9.8	22.8	56.6	91.2
Total equity	**125.6**	**164.6**	**197.2**	**231.0**	**265.6**

Leverage Ratios	FY22	FY23	FY24e	FY25e	FY26e
Net debt/(cash)	-121.5	-156.8	-190.1	-222.6	-255.3
Net debt/equity (x)	nm	nm	nm	nm	nm
Net debt/assets (x)	nm	nm	nm	nm	nm
Net debt/EBITDA (x)	nm	nm	nm	nm	nm

Revenue Analysis (A$m)	FY22	FY23	FY24e	FY25e	FY26e
Scenesse (risk-adjusted)	65.7	78.3	85.9	93.0	102.6
Neuracthel (risk-adjusted)	0.0	0.0	0.0	0.0	0.0
Prenumbra (risk-adjusted)	0.0	0.0	0.0	0.0	0.0
PhotoCosmetics	0.0	0.0	0.1	0.2	0.5
Total revenue	65.7	78.3	86.0	93.2	103.1
Growth (%)	*nm*	*19%*	*10%*	*8%*	*11%*

Interim Results	1H23	2H23	1H24	2H24e
Revenue	29.4	49.0	32.3	53.7
EBITDA	13.6	28.8	11.7	32.5
NPAT (pre abnormals)	11.4	19.2	10.9	24.1

SOURCE: BELL POTTER SECURITIES ESTIMATES

Recommendation structure

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

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

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

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

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

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