# Cadila Healthcare

02 March 2021

Reuters: CADI.NS; Bloomberg: CDH IN

Company Update

## CUTX-101 – Approval prospects high and can be a decent opportunity

**Cadila Healthcare recently announced the acquisition of experimental drug – CUTX-101 (copper histidinate) from Cyprium for treating the Menkes disease. Menkes disease is a genetic paediatric disorder caused by gene mutations of copper transporter ATP7A. CUTX-101 is currently in Phase 3 development and as per the agreement terms, Cadila will make an upfront cash payment of US$20mn to Cyprium. Cadila will also and also provide additional cash payments upon achievement of certain regulatory milestones, besides paying royalties and commercial milestone payments based on the net sales of CUTX-101. Depending on the sales level, royalties will range between mid-single-digit to mid-twenties as a percentage of sales. The NDA submission will happen anytime this year and approval will be expedited considering that the drug is granted breakthrough designation.**

**Cyprium will retain development responsibility for CUTX-101 through approval of the New Drug Application (NDA) by the United States Food & Drug Administration (USFDA). Sentynl will be responsible for the commercialization of CUTX-101 as well as progressing new-born screening activities. Continued development of CUTX-101 will be overseen by a Joint Steering Committee consisting of representatives from Cyprium and Sentynl.**

**About the Menkes disease:** The Menkes disease is a rare X-linked recessive paediatric disease caused by gene mutations of copper transporter ATP7A. Biochemically, patients with the Menkes disease have low levels of copper in their blood and brain as well as abnormal levels of certain neurochemicals. Definitive diagnosis is made by sequencing the ATP7A gene. The condition is characterized by distinctive clinical features, including sparse and de-pigmented hair ("kinky hair"), connective tissue problems and severe neurological symptoms such as seizures, hypotonia, failure to thrive, and neuro developmental delays. Mortality is high in untreated Menkes disease, with many patients dying before the age of three years. The minimum birth prevalence for the Menkes disease is believed to be 1 in 34,810 males and potentially as high as 1 in 8,664 live male births, based on the recent genome-based ascertainment , which translates into an annual incidence of 54 to 225 patients. Currently, there is no FDA-approved treatment for the Menkes disease and its variants and copper histidinate is used off label.

**Clinical evidence on CUTX-101 in the Menkes disease:** CUTX-10 has been granted Breakthrough Therapy Designation. The criteria for Breakthrough Therapy Designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A Breakthrough Therapy Designation conveys all of the fast-track program features, more intensive FDA guidance on an efficient drug development program, an organizational commitment involving senior managers and eligibility for rolling review and priority review. Since Menkes is a rare disease, CUTX-101 has also been granted orphan drug designation. A Phase 1/2 clinical trials demonstrated that early treatment of patients with Menkes disease with CUTX-101 led to an improvement in neurodevelopmental outcomes and survival. A Phase 3 trial of CUTX-101 in patients with the Menkes disease is also underway. In August 2020, Cyprium reported positive top line clinical efficacy results for CUTX-101, demonstrating statistically significant improvement in overall survival for Menkes disease subjects who received early treatment (ET) with CUTX-101, compared to an untreated historical control (HC) cohort, with a nearly 80% reduction in the risk of death.

| Y/E March (Rsmn) | FY 19 | FY20 | FY21E | FY22E | FY23E |
|---|---|---|---|---|---|
| Net sales | 1,31,656 | 1,42,531 | 1,51,404 | 1,61,887 | 1,74,441 |
| EBITDA | 29,731 | 27,834 | 33,029 | 34,198 | 36,138 |
| Net profit | 18,488 | 11,766 | 19,195 | 20,011 | 20,945 |
| EPS (Rs) | 18 | 11.5 | 18.8 | 19.5 | 20.4 |
| *EPS growth (%)* | *4.1* | *(36.4)* | *63.1* | *4.2* | *4.6* |
| *EBITDA margin (%)* | *22.6* | *19.5* | *21.8* | *21.1* | *20.7* |
| PER (x) | 24.1 | 37.8 | 23.2 | 22.3 | 21.3 |
| P/BV (x) | 4.3 | 4.3 | 3.7 | 3.3 | 2.9 |
| EV/EBITDA (x) | 17.2 | 18.2 | 14.9 | 14.2 | 13.2 |
| *RoCE (%)* | *15.6* | *10.1* | *18.8* | *18.7* | *19.2* |
| *RoE (%)* | *17.8* | *11.3* | *15.8* | *15.0* | *14.0* |

*Source: Company, Nirmal Bang Institutional Equities Research*

## ACCUMULATE

**Sector:** Pharmaceuticals

**CMP:** Rs435

**Target Price:** Rs470

**Upside:** 8%

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**Key Data**

| | |
|---|---|
| Current Shares O/S (mn) | 1,023.7 |
| Mkt Cap (Rsbn/US$bn) | 445.6/6.1 |
| 52 Wk H / L (Rs) | 509/202 |
| Daily Vol. (3M NSE Avg.) | 3,718,930 |

**Price Performance (%)**

| | 1 M | 6 M | 1 Yr |
|---|---|---|---|
| Cadila Healthcare | (6.8) | 14.0 | 74.0 |
| Nifty Index | 0.8 | 28.0 | 32.6 |

*Source: Bloomberg*

Latest Annual Report
Latest Quarterly Result

### Peak Revenue of CUTX-101 in the US

**The annual incidence rate of Menkes disease is somewhere between 54 patients and 225 patients in the US. The revenue potential from CUTX-101 would be determined primarily by pricing. Current trends in orphan drug pricing suggest that lower the incidence rate, higher is the pricing. The median pricing stands at ~US$150,000 per patient per year.** The drugs that fetch the highest price per patient per year are Soliris and Naglazyme, which fetch over US$500,000 per patient per year. These drugs treat the lowest number of patients per year. Naglazyme, which is marketed by BioMarin Pharmaceuticals, is indicated for Maroteaux-Lamy disease and was used to treat fewer than 200 patients in 2018. While Soliris, marketed by Alexion Pharmaceuticals and indicated for Paroxysmal nocturnal haemoglobinuria (PNH), was used to treat just under 3,000 patients. Depending on the pricing peak revenue for CUTX-101 can vary between US$50mn and US$150mn in the US.

**Approval prospects:** The company is expected to begin the rolling submission process anytime now and we should potentially expect an approval by the end of CY21. Since CUTX-101 has been granted breakthrough designation and there are no approved treatment options, we expect the approval to come through. We are currently not including the drug in our forecasts and would do so once we have a better sense on the approval timelines.

**Outlook and valuation:** Potential price erosion in its limited competition asset gAsacol HD in the US on account of generic competition (Para III filers) in FY22 is the key overhang for Cadila. It is difficult to predict the extent of erosion in gAsacol HD post expiry of the last patent in FY22 (Nov'21). Asacol HD is a complex formulation (scale up and clinical bioequivalence is a challenge). Cadila has a pipeline of injectable and transdermal patches, which could more than compensate for the erosion, but the upside in earnings from the same would be gradual and happen over FY22-FY23. The resultant effect on earnings would be driven by the pace of erosion in Asacol HD and ramp-up of new limited competition/complex generic assets. Incrementally, Cadila is rolling out its biosimilar portfolio in EMs and we expect traction in earnings on account of this FY22 onwards. We retain our estimates on Cadila and assign Accumulate rating with a target price of Rs470.

# Financial statements: Cadila Healthcare

## Exhibit 2: Income statement

| Y/E March (Rsmn) | FY19 | FY20 | FY21E | FY22E | FY23E |
|---|---|---|---|---|---|
| **Net sales** | **1,31,656** | **1,42,531** | **1,51,404** | **1,61,887** | **1,74,441** |
| *% growth* | *10.3* | *8.3* | *6.2* | *6.9* | *7.8* |
| Raw material costs | 47,164 | 49,200 | 52,072 | 56,082 | 61,190 |
| Staff costs | 21,241 | 24,145 | 25,096 | 27,104 | 29,272 |
| R&D expenses | 9,422 | 10,974 | 8,062 | 10,120 | 10,790 |
| Other expenditure | 33,520 | 41,352 | 41,207 | 44,504 | 47,841 |
| Total expenditure | 1,01,925 | 1,14,697 | 1,18,375 | 1,27,689 | 1,38,303 |
| **EBITDA** | **29,731** | **27,834** | **33,029** | **34,198** | **36,138** |
| *% growth* | *4.4* | *-6.4* | *18.7* | *3.5* | *5.7* |
| *EBITDA margin (%)* | *22.6* | *19.5* | *21.8* | *21.1* | *20.7* |
| Other income | 2,011 | 1,139 | 1,050 | 1,409 | 1,410 |
| Interest costs | 1,935 | 3,418 | 1,670 | 1,545 | 1,545 |
| **Gross profit** | **84,492** | **93,331** | **99,332** | **1,05,805** | **1,13,251** |
| *% growth* | *8.1* | *10.5* | *6.4* | *6.5* | *7.0* |
| Depreciation | 5,986 | 6,965 | 7,166 | 7,714 | 8,128 |
| **Profit before tax & Exceptional Items** | **23,821** | **18,590** | **25,243** | **26,348** | **27,875** |
| Exceptional Items | 0 | -3,636 | -1,320 | 0 | 0 |
| **Profit before tax** | 23,821 | 14,954 | 23,923 | 26,348 | 27,875 |
| *% growth* | *2.2* | *-22.0* | *35.8* | *4.4* | *5.8* |
| Tax | 5,303 | 3,198 | 5,110 | 6,186 | 6,680 |
| *Effective tax rate (%)* | *22* | *17* | *20* | *23* | *24* |
| **PAT before Minority Interest** | **18,518** | **11,756** | **18,813** | **20,161** | **21,195** |
| Share of JV | 469 | 288 | 550 | 550 | 550 |
| Share of MI and Associates | -499 | -278 | -168 | -700 | -800 |
| **PAT after Minority Interest** | **18,488** | **11,766** | **19,195** | **20,011** | **20,945** |
| *% growth* | *4.8* | *-36.5* | *60.0* | *7.2* | *5.1* |
| **EPS (Rs)** | **18.1** | **11.5** | **18.8** | **19.5** | **20.4** |

*Source: Company, Nirmal Bang Institutional Equities Research*

## Exhibit 4: Balance sheet

| Y/E March (Rsmn) | FY19 | FY20 | FY21E | FY22E | FY23E |
|---|---|---|---|---|---|
| Equity | 1,024 | 1,024 | 1,024 | 1,024 | 1,024 |
| Reserves | 1,02,839 | 1,02,733 | 1,17,836 | 1,33,755 | 1,50,608 |
| Net worth | 1,03,863 | 1,03,757 | 1,18,860 | 1,34,779 | 1,51,632 |
| Minority Interest | 12,929 | 13,347 | 13,347 | 13,347 | 13,347 |
| Net deferred tax liabilities | 3,060 | 2,390 | 2,390 | 2,390 | 2,390 |
| Total Loans | 71,466 | 70,411 | 50,234 | 49,198 | 40,719 |
| Other Non-Current Liabilities | 2,594 | 2,823 | 2,823 | 2,823 | 2,823 |
| **Liabilities** | **1,93,912** | **1,92,728** | **1,87,654** | **2,02,537** | **2,10,911** |
| Net Block + CWIP | 51,059 | 54,522 | 69,522 | 74,522 | 79,522 |
| CWIP | 8,372 | 7,415 | 7,415 | 7,415 | 7,415 |
| Intangible Assets and Goodwill | 70,578 | 67,783 | 67,783 | 67,783 | 67,783 |
| Other Non-Current Assets | 13,166 | 11,610 | 11,610 | 11,610 | 11,610 |
| Non-Current Investments | 6,675 | 8,382 | 8,382 | 8,382 | 8,382 |
| Inventories | 26,880 | 27,890 | 28,640 | 30,845 | 33,654 |
| Debtors | 39,508 | 36,632 | 35,832 | 39,910 | 43,009 |
| Cash | 5,489 | 9,649 | 3,225 | 7,563 | 9,703 |
| Other current assets | 13,104 | 12,983 | 12,983 | 12,983 | 12,983 |
| Total current assets | 84,981 | 87,154 | 80,681 | 91,300 | 99,349 |
| Creditors | 19,226 | 20,310 | 23,953 | 24,115 | 26,312 |
| Other current liabilities | 21,693 | 23,828 | 33,785 | 34,360 | 36,839 |
| Total current liabilities | 40,919 | 44,138 | 57,739 | 58,475 | 63,151 |
| Net current assets | 44,062 | 43,016 | 22,942 | 32,825 | 36,199 |
| **Total assets** | **1,93,912** | **1,92,728** | **1,87,654** | **2,02,537** | **2,10,911** |

*Source: Company, Nirmal Bang Institutional Equities Research*

## Exhibit 3: Cash flow

| Y/E March (Rsmn) | FY19 | FY20 | FY21E | FY22E | FY23E |
|---|---|---|---|---|---|
| EBIT | 23,821 | 14,954 | 24,473 | 26,898 | 28,425 |
| (Inc.)/Dec. in working capital | -9,717 | 1,294 | 13,650 | -5,546 | -1,233 |
| **Cash flow from operations** | **14,104** | **16,248** | **38,123** | **21,352** | **27,192** |
| Other income | -1,664 | -591 | -1,050 | -1,409 | -1,410 |
| Other Expenses | 1,069 | 5,453 | 900 | 2,095 | 2,095 |
| Depreciation | 5,986 | 6,965 | 7,166 | 7,714 | 8,128 |
| Tax paid (-) | -6,754 | -3,025 | -5,110 | -6,186 | -6,680 |
| **Net cash from operations** | **12,819** | **25,054** | **40,029** | **23,565** | **29,325** |
| Capital expenditure (-) | -10,464 | -8,888 | -22,166 | -12,714 | -13,128 |
| **Net cash after capex** | **2,355** | **16,166** | **17,863** | **10,851** | **16,197** |
| **Other Investing activities** | **-31,923** | **-1,235** | **1,050** | **1,409** | **1,410** |
| **Cash from Financial Activities** | **18,846** | **-10,942** | **-25,337** | **-7,923** | **-15,466** |
| Opening cash | 15,897 | 7,788 | 9,649 | 3,225 | 7,563 |
| Closing cash | 7,788 | 11,777 | 3,225 | 7,563 | 9,703 |
| Change in cash | -10,722 | 3,989 | -6,424 | 4,337 | 2,141 |

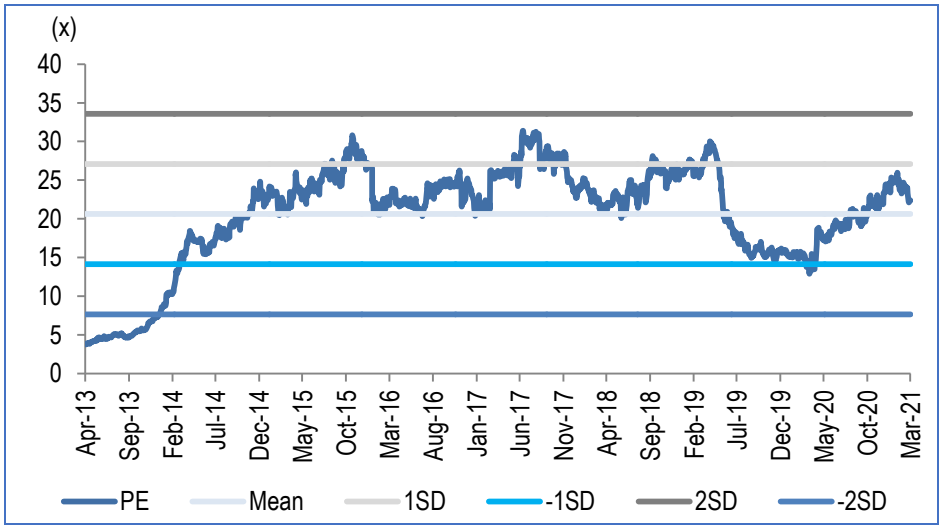
*Source: Company, Nirmal Bang Institutional Equities Research*

## Exhibit 5: Key ratios

| Y/E March | FY19 | FY20 | FY21E | FY22E | FY23E |
|---|---|---|---|---|---|
| **Profitability & return ratios** | | | | | |
| EBITDA margin (%) | 22.6 | 19.5 | 21.8 | 21.1 | 20.7 |
| EBIT margin (%) | 19.6 | 15.4 | 17.8 | 17.2 | 16.9 |
| Net profit margin (%) | 14.1 | 8.2 | 12.4 | 12.5 | 12.2 |
| RoE (%) | 17.8 | 11.3 | 15.8 | 15.0 | 14.0 |
| RoCE (%) | 15.6 | 10.1 | 18.8 | 18.7 | 19.2 |
| **Working capital & liquidity ratios** | | | | | |
| Receivables (days) | 99 | 97 | 87 | 85 | 87 |
| Inventory (days) | 196 | 203 | 198 | 194 | 192 |
| Payables (days) | 147 | 147 | 155 | 156 | 150 |
| Current ratio (x) | 2.1 | 2.0 | 1.4 | 1.6 | 1.6 |
| Quick ratio (x) | 1.4 | 1.3 | 0.9 | 1.0 | 1.0 |
| **Valuation ratios** | | | | | |
| EV/sales (x) | 3.9 | 3.6 | 3.3 | 3.0 | 2.7 |
| EV/EBITDA (x) | 17.2 | 18.2 | 14.9 | 14.2 | 13.2 |
| P/E (x) | 24.1 | 37.8 | 23.2 | 22.3 | 21.3 |
| P/BV (x) | 4.3 | 4.3 | 3.7 | 3.3 | 2.9 |

*Source: Company, Nirmal Bang Institutional Equities Research*

## P/E Chart

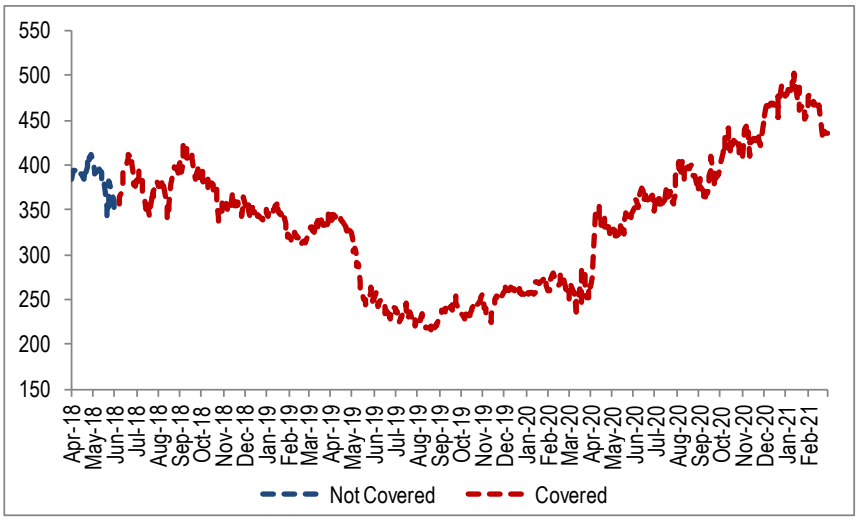



*Source: BSE, Bloomberg, Company, Nirmal Bang Institutional Equities Research*

## Rating track

| Date | Rating | Market price (Rs) | Target price (Rs) |
|---|---|---|---|
| 7June 2019 | Buy | 247 | 315 |
| 13August 2019 | Buy | 230 | 315 |
| 23 September 2019 | Buy | 247 | 314 |
| 14 November 2019 | Buy | 225 | 314 |
| 3 February 2020 | Buy | 260 | 314 |
| 6 February 2020 | Buy | 272 | 314 |
| 27 March 2020 | Buy | 257 | 311 |
| 23 April 2020 | Sell | 331 | 311 |
| 19 June 2020 | Sell | 362 | 331 |
| 5 August 2020 | Sell | 396 | 381 |
| 23 September 2020 | Accumulate | 393 | 442 |
| 29 September 2020 | Accumulate | 391 | 442 |
| 3 November 2020 | Accumulate | 418 | 442 |
| 07 January 2021 | Accumulate | 482 | 475 |
| 13 January 2021 | Accumulate | 490 | 475 |
| 08February 2021 | Accumulate | 475 | 470 |
| 02 March 2021 | Accumulate | 435 | 470 |

## Rating track graph



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ACCUMULATE -5% to15%

SELL < -5%

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