July 26, 2019

# Torrent Pharmaceuticals Limited: Ratings placed under watch with negative implications

## Summary of Rated Instrument:

| Instrument* | Previous Rated Amount (Rs. crore) | Current Rated Amount (Rs. crore) | Rating Action |
|---|---|---|---|
| Non-convertible debenture programme | 3,100.00 | 3,100.00 | [ICRA]AA@; placed on ratings watch with negative implications |
| Commercial paper | 560.00 | 560.00 | [ICRA] A1+@; placed on ratings watch with negative implications |
| Fund-based term loan | 197.67 | 1797.67 | [ICRA]AA@; placed on ratings watch with negative implications |
| Fund-based working capital facilities | 1,795.00 | 1,795.00 | [ICRA]AA@; placed on ratings watch with negative implications |
| **Total** | **7,252.67** | **7,252.67** | |

@- ratings under watch with negative Implications

## Material Event

On July 17, 2019, the US Food and Drug Administration (USFDA) classified Torrent Pharmaceuticals Limited's (TPL) Dahej facility (Gujarat) under Official Action Indicated (OAI). This relates to the inspection carried out in March 2019 when the company had received 483s from the USFDA.

## Rationale

ICRA has placed the ratings of TPL on ratings watch with negative implications following the pending resolution of OAI on TPL's Dahej plant coupled with pending resolution of 483s for the Indrad (Gujarat) plant in March 2019 and April 2019, respectively. These facilities together account for majority of the existing revenues of TPL's US operations in addition to ANDA filings for future launches. Dahej facility contributes a smaller portion of US revenues (~15%) in addition to servicing regulated markets of Europe while Indrad supplies primarily to the US market. The US market contributed 20.7% of the FY2019 revenues and 18.6% of revenues in Q1 FY2020 and therefore resolution of these observations remains key to the company's operations. The risk is partly mitigated owing to diversified geographical presence in other regulated (Germany) and semi-regulated markets (Brazil, India, RoW). Additionally, the classification to OAI does not disrupt the existing supplies to the US thereby only delaying new launches till OAI status of Dahej is resolved.

Torrent Pharmaceuticals Limited reported net margins of 5.7% in FY2019 compared to 11.4% in FY2018 as a result of one-time expenses of Rs. 357 crore taken during Q4FY2019. An exceptional charge of Rs. 217 crore was taken towards impairment provision of certain intangible assets, and goodwill recognized with respect to the acquisition of Bio-Pharm, Inc (Levittown Pennsylvania, USA). Additionally, a provision of Rs. 140 crore was taken by the company in relation to product recalls (Losartan recall) and associated expenses that include write down of inventory, contractual obligations and recall expenses.

With the debt-funded acquisitions of Unichem Laboratories Limited (Unichem) and Bio-pharm in FY2018, TPL's debt levels rose significantly impacting its coverage indicators. On a consolidated basis, gross debt/OPBDITA increased from 1.8 times in FY2017 to 4.8 times in FY2018 and 3.0 times in FY2019, while net debt/OPBDITA increased from 0.6 times in FY2017 to 3.8 times in FY2018 and 2.4 times in FY2019. The company's debt coverage indicators were expected to improve going forward, as synergies from the Unichem acquisition flows in. ICRA will monitor the impact of various regulatory developments including successful resolution of USFDA observations for its manufacturing facilities, impact on US ANDA filings & future launches, adequacy of product recall provisions & recurrence of such events and its impact on leverage indicators in the near to medium term. However, the ratings take comfort from ample liquidity, healthy accruals and long-tenure debt providing cushion for debt repayments.

The ratings continue to favourably factor TPL's established presence in the domestic market (44.9% as in Q1FY2020) driven by organic and inorganic growth and its diversified international business operations in the key markets of USA (18.6%), Germany (13.0%) and Brazil (8.6%). It has limited coverage under the drug price control order (DPCO) at ~11% versus the Indian pharmaceutical market (IPM) that stands at around 18%. The ratings also take into account TPL's continued focus on recurring and lifestyle-related chronic/sub-chronic therapies, which comprise 75% of its portfolio. It is the seventh largest domestic player (without bonus units) with a market share of 3.35% and ranks amongst the top five players in the key therapeutic areas of cardiovascular (CV), central nervous system (CNS), vitamin minerals nutrients (VMN) and gastrointestinal (GI). The company continues to strengthen its domestic product profile by launching products and brand extensions with 25 launches in FY2017, 24 in FY2018 and 16 in FY2019. Post the acquisition of Unichem, the market share for the combined business has grown across all therapeutic areas, with nine brands generating more than Rs. 100 crore revenues as per AIOCD MAT data (June 2019). As per AIOCD MAT March 2019, the top five brands acquired from Unichem grew at 15% in FY2019 compared to its covered market growth of 12% for the same period.

TPL's international operations have shown consistent profitability at an aggregate level; although, ICRA notes that in certain international markets, TPL faces volatility in performance owing to various regulatory and legal challenges especially, the US market that is facing pricing pressure on account of faster abbreviated new drug application (ANDA) and consolidation in the distribution supply chain. TPL's US business has shown high volume growth by leveraging the supply gaps created by the exit of big pharmaceutical companies, though the desired profitability is expected to be achieved over the medium term. The company continues to maintain its R&D spend at 7-8%, resulting in a healthy pipeline and basket of ANDA filings for the international markets, especially the US. TPL is ramping up its pipeline with products in oral liquids, ophthalmic, ointment and oncology.

Overall, at a consolidated level, the company generated healthy operating margins of 22.6% in FY2018, 25.8% in FY2019 and 25.9% in Q1 FY2020. The liquidity on a standalone basis (Rs. 589.3 crore of cash and liquid investments as of March 2019) and consolidated basis (Rs. 1230.0 crore as of March 2019), along with the substantial undrawn bank limits, provides comfort to the company's overall financial profile. TPL's modest current capex requirement will lead to positive free cash flows; however, any additional debt-funded acquisition will need to be evaluated. The company's debt coverage indicators are expected to improve going forward, as synergies from the Unichem acquisition flows in. Going forward, the company's ability to sustain its performance across multiple geographies, resolving the existing USFDA observations for its manufacturing facilities, and reducing its leverage would remain critical in sustaining its financial profile.

## Outlook: Not applicable

## Key rating drivers

## Credit strengths

**Established position in domestic formulations market, with strong presence in the fast-growing life style related therapeutic segments and successful integration of Unichem acquisition** - The company is currently ranked seventh (without bonus units) in the IPM with a market share of 3.35% in FY2019. It ranks amongst the top five players in key therapeutic areas of CV, CNS, VMN, and GI. The company's 19 brands are in the top 500 brands of the IPM with nine brands generating more than Rs. 100 crore revenues as per AIOCD MAT data (June 2019). Brands like Shelcal, Losar, Nexpro, Chymoral, Nebicard, Deplatt, Azulix etc have contributed significantly to the domestic sales, strengthening the company's position in key therapies. As per AIOCD MAT March 2019, the top five brands acquired from Unichem grew at 15% in FY2019 compared to its covered market growth of 12% for the same period. TPL benefits from integration and realisation of cost synergies including optimisation of field forces (productivity of medical representatives improved to 7.2 lakhs in Q1 FY2020 compared to 6.2 lakhs in FY2019), brand building, speciality focus and improving the sales representatives' in-clinic effectiveness. Losar, stands at Rs. 217 crore and grew at 11% versus 2% in the covered market. TPL's other brands, such as Shelcal grew at 28% versus 9% in the covered market and Chymoral grew at 29% versus 16% in the covered market[1].

**Diversified international operations with focus on regulated/semi-regulated generics market through consistent R&D spend and filings** - TPL has diversified operations across the US (18.6%), Brazil (8.6%), Germany (13.0%), and rest of the world (RoW) countries (8.9%) of consolidated revenues in Q1 FY2020. TPL markets both branded generics to semi-regulated markets (India and Brazil) and unbranded generics to regulated markets (the US and Germany). It also participates in the institutional segment of export markets.

The company's growth strategy in the international markets is growth via new product launches and higher volumes sold. In line with its new product launches, TPL increased its R&D spend to 7.2% in FY2019 from 5.0% in FY2016, and expects to maintain it at 7-8% of revenues going forward. It intends to focus on complex and niche filings for the US market, primarily in the space of oral liquids, ophthalmic, ointment and oncology. As of March 2019, the company received 14 ANDA approvals in FY2019. The company has 100 ANDA approvals (including 11 tentative approvals) and its pipeline consists of 34 pending approvals for US business. The company also has a healthy pipeline of products under approval and development in Brazil. Meanwhile in Germany, TPL typically launches 8-10 products annually, with four-five being launched on day one. With the increased thrust on R&D, the share of international markets is expected to increase over the medium term and is likely to complement the profitability.

**Healthy operating profitability led by profitable domestic as well as international businesses at aggregate level; net profitability impacted due to one-time provisioning in FY2019** - TPL continues to generate healthy operating margins by virtue of its high-margin domestic business as well as profitable international operations at an aggregate level. The operating margins stood at 22.6% in FY2018, 25.8% in FY2019 and 26.8% in Q1 FY2020. While US is experiencing pricing pressure the profitability is supported by other key markets, such as Germany, RoW countries and India.

The net margins reduced to 5.7% in FY2019 from 11.4% in FY2018 due to one-time provisioning of Rs. 357 crore during the year. TPL wrote down an exceptional charge of Rs. 217 crore towards impairment provision of certain intangible assets, and goodwill recognized with respect to the acquisition of Bio-Pharm in June 2018. Additionally, the company provisioned for Rs. 140 crore in relation to product recalls (Losartan recall) and associated expenses that include write down of inventory, contractual obligations and recall expenses.

**Liquidity position supported by liquid investments and undrawn working capital lines** - TPL had ample liquidity in the form of liquid investments, and cash and bank balances to the tune of Rs. 1,359.5 crore and Rs. 1230.0 crore in FY2018 and FY2019, respectively, on a consolidated basis. On a standalone basis also, the company had Rs. 532.4 crore and Rs. 589.3 crore in liquid investments, and cash and bank balances in FY2018 and FY2019 respectively. The surplus funds in its

[1] Source: AIOCD MAT (March 2019)

overseas subsidiaries can be freely remitted to India. The company also enjoys a buffer in the form of undrawn bank lines, which supports its liquidity position.

## Credit challenges

**Moderately high coverage indicators due to significant debt-funded acquisitions; expected to improve in the near term -** With the debt-funded acquisitions of Unichem and Bio-pharm in FY2018, TPL's debt levels rose significantly impacting its coverage indicators. On a consolidated basis, gross debt/OPBDITA increased from 1.8 times in FY2017 to 4.8 times in FY2018 and 3.0 times in FY2019, while net debt/OPBDITA increased from 0.6 times in FY2017 to 3.8 times in FY2018 and 2.4 times in FY2019. The company's debt coverage indicators are expected to improve going forward, as synergies from the Unichem acquisition flows in. ICRA will monitor the impact of various regulatory developments including successful resolution of USFDA observations for its manufacturing facilities, adequacy of product recall provisions & recurrence of such events and its impact on leverage indicators in the near to medium term. However, the ratings take comfort from ample liquidity, healthy accruals and long-tenure debt providing cushion for debt repayments.

**Sustaining profitability of exports by continuing to build up size through product launches and market expansion** - TPL's international generic business is characterised by pricing pressure and it is essential to launch new products to maintain profitability. While TPL has built significant scale for its Brazil and German operations, it is yet to achieve a significant scale for the largest generic market of the US.

**Managing legal and regulatory changes in various markets** - The company is continuously exposed to regulatory changes in Indian and global markets. These are reflected in the increasing scrutiny and inspections by regulatory authorities, including the USFDA. The company had received 483s for its two plants at Dahej (Gujarat) and Indrad (Gujarat) in March 2019 and April 2019, respectively. These facilities together account for more than 90% of revenues of TPL's US operations. Dahej facility contributes a smaller portion of US revenues (~15%) in addition to servicing regulated markets of Europe while Indrad, supplies primarily to the US market. The US market constitutes 20.7% of the FY2019 revenues and 18.6% of revenues in Q1 FY2020 therefore resolution of these observations remains key to the company's operations. The risk is mitigated to an extent, as US revenues constitute a smaller portion of the company's revenues compared to its presence in other regulated and semi-regulated markets. Additionally, the classification to OAI does not disrupt the existing supplies to the US thereby only delaying new launches till OAI status of Dahej is resolved. In the domestic market, regulatory impact of policy changes such as the DPCO and the fixed dose combinations (FDC) was relatively small on TPL, though further policy changes such as compulsory genericisation can have a major impact on TPL and the industry as a whole.

## Liquidity position

The company generated positive FFO for the last five years, though capex requirement and previous debt-funded acquisitions led to negative free cash flows in FY2019. TPL's ongoing capex requirement has moderated to Rs. 300-350 crore; however, any further acquisition in the near term will impact its cash flows adversely. The liquidity profile remains supported by the company's ability to refinance debt, the sufficient liquid investments, the cash and bank balances, and the low utilisation of existing working capital limits.

## Analytical approach

| Analytical Approach | Comments |
|---|---|
| Applicable Rating Methodologies | Corporate Credit Rating Methodology<br>Rating Methodology for Entities in the Pharmaceutical Industry |
| Parent/Group Support | Not Applicable |
| Consolidation/Standalone | For arriving at the ratings, ICRA has considered the consolidated financials of TPL. As on June 30, 2019, the company had 12 subsidiaries and four step-down subsidiaries which are listed in Annexure-2. |

## About the company

TPL is the seventh largest player (without bonus units) in the domestic market with a significant market share of 3.35% in FY2019. The company also has an arrangement with Novo Nordisk for the manufacture and supply of insulin in the domestic market. TPL's export business is carried out both by its foreign subsidiaries as well as directly by the parent company. The company has eight manufacturing plants approved by multiple authorities like the USFDA, EU, MHRA (UK) and ANVISA (Brazil).

In FY2006, TPL acquired Heumann Pharma GmbH & Co. Generica KG (Heumann), a Pfizer Group company, involved in generic medicines marketing in Germany. In June 2014, TPL acquired Elder Pharma's branded domestic formulation business in India and Nepal for a consideration of Rs. 2,004 crore. Elder's acquired business comprised a portfolio of 30 brands including leading brands for women's healthcare (WHC), pain management, wound care and neutraceuticals therapeutic segment. The acquisition complemented TPL's existing therapies and provided a strong foothold in neutraceuticals/WHC segment and pain segment. In May 2017, TPL acquired two hormonal brands from Novartis AG for the Indian market. This acquisition further added to TPL's established position in the WHC segment. With the acquisition of ZYG Pharma's USFDA approved facility, the company embarked into the niche dermatological segment, especially in the developed markets of North America and Europe and the emerging markets of India and Brazil. In December 2017, TPL acquired the branded business of Unichem (India and Nepal) for Rs. 3515.0 crore, strengthening its position in the key segments of cardiology, diabetology, gastrointestinal and CNS therapies. Following this, TPL also acquired Bio-pharm in January 2018 to establish its presence in the US. The USFDA approved facility provides capabilities for controlled substances, which can be manufactured in the US only as per Government guidelines (DEA Schedule II-V).

## Key financial indicators (audited)

| | FY2017 | FY2018 | FY2019 |
|---|---|---|---|
| Operating Income (Rs. crore) | 5,856.9 | 5949.8 | 7672.8 |
| PAT (Rs. crore) | 933.6 | 678.1 | 436.3 |
| OPBDIT/OI (%) | 23.5% | 22.7% | 25.8% |
| RoCE (%) | 23.5% | 14.6% | 10.2% |
| | | | |
| Total Debt/TNW (times) | 0.6 | 1.4 | 1.3 |
| Total Debt/OPBDIT (times) | 1.8 | 4.8* | 3.0 |
| Net Debt/OPBDIT (times) | 0.6 | 3.8 | 2.4 |
| Interest Coverage (times) | 6.7 | 4.4 | 3.9 |

**Owing to Unichem portfolio acquisition In Dec 2017, TD/OPBITDA for FY2018 is not comparable across years*

## Status of non-cooperation with previous CRA: Not applicable

## Any other information: None

## Rating history for last three years

| | | Current Rating (FY2020) | | | | | Chronology of Rating History for the Past 3 Years | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | Amount Rated (Rs. crore) | Amount Outstanding (Rs. crore) | Date & Rating | | Date & Rating in FY2019 | Date & Rating in FY2019 | Date & Rating in FY2017 |
| | Instrument | Type | | | July 2019 | May 2019 | May 2018 | Jan 2018 | Sept 2016 |
| 1 | NCD | Long term | 3,100.0 | 1873.95 | **[ICRA]AA @** | [ICRA]AA (Stable) | [ICRA]AA (Stable) | [ICRA]AA& | [ICRA]AA (Positive) |
| 2 | Commercial paper | Short term | 560.0 | 291.66 | **[ICRA]A1+ @** | [ICRA]A1+ | [ICRA]A1+ | [ICRA]A1+& | [ICRA]A1+ |
| 3 | Term loans | Long term | 1797.67 | 1589.12 | **[ICRA]AA @** | [ICRA]AA (Stable) | [ICRA]AA (Stable) | [ICRA]AA& | [ICRA]AA (Positive) |
| 4 | Working capital | Long term | 1,795.0 | - | **[ICRA]AA @** | [ICRA]AA (Stable) | [ICRA]AA (Stable) | [ICRA]AA& | [ICRA]AA (Positive) |
| 5 | Proposed long-term facility | Long term | 0.00 | - | - | - | [ICRA]AA (Stable) | [ICRA]AA& | - |

*Note: &- ratings under watch with developing Implications*
*Note: @- ratings under watch with negative Implications*

## Complexity level of the rated instrument

ICRA has classified various instruments based on their complexity as "Simple", "Complex" and "Highly Complex". The classification of instruments according to their complexity levels is available on the website www.icra.in

## Annexure-1: Instrument Details

| ISIN No | Instrument Name | Date of Issuance/ Sanction | Coupon Rate | Maturity Date | Amount Rated (Rs. crore) | Current Rating and Outlook |
|---|---|---|---|---|---|---|
| INE685A07041 | NCD | Jun. 24, 2015 | 9.20% | Jun. 24, 2020 | 83.00 | [ICRA]AA@ |
| INE685A07058 | NCD | Jun. 24, 2015 | 9.20% | Mar. 26, 2018<br>Mar. 25, 2019<br>Mar. 24, 2020 | 240.00 | [ICRA]AA@ |
| INE685A07066 | NCD | Dec. 13, 2016 | 7.95% | Dec. 13, 2018<br>Dec. 13, 2019<br>Dec. 14, 2020<br>Dec. 13, 2021 | 500.00 | [ICRA]AA@ |
| INE685A07074 | NCD | Dec. 29, 2016 | 7.80% | Dec. 28, 2018<br>Dec. 27, 2019<br>Dec. 29, 2020 | 500.00 | [ICRA]AA@ |
| INE685A07082 | NCD | Dec. 14, 2017 | 7.98%* | Dec. 13, 2019<br>Dec. 14, 2020<br>Dec. 14, 2021<br>Dec. 14, 2022<br>Dec. 14, 2023<br>Dec. 13, 2024<br>Dec. 12, 2025 | 1000.00 | [ICRA]AA@ |
| NA | Commercial paper | NA | NA | 7-365 days | 560.00 | [ICRA]A1+@ |
| NA | Term loan 1 | Dec. 2013 | NA | Jun. 30,2022 | 95.41 | [ICRA]AA@ |
| NA | Term loan 2 | Dec. 2013 | NA | Jun. 30,2022 | 70.78 | [ICRA]AA@ |
| NA | Term loan 3 | Dec. 2013 | NA | Jun. 30,2022 | 31.48 | [ICRA]AA@ |
| NA | Term Loan 4 | Dec. 2017 | NA | Dec. 12, 2025 | 1000.00 | [ICRA]AA@ |
| NA | Term loan 5 | Dec. 2017 | NA | Sep. 14 2025 | 600.00 | [ICRA]AA@ |
| NA | Working capital facility | NA | NA | NA | 1,795.00 | [ICRA]AA@ |

*Source: Company, @- ratings under watch with negative implications*

## Annexure-2: List of entities considered for consolidated analysis

| Company Name | Ownership | Consolidation Approach |
|---|---|---|
| Zao Torrent Pharma | 100.00% | Full Consolidation |
| Torrent Pharma Gmbh | 100.00% | Full Consolidation |
| Torrent Do Brasil Ltda. | 100.00% | Full Consolidation |
| Torrent Pharma Inc. | 100.00% | Full Consolidation |
| Torrent Pharma Philipine Inc. | 100.00% | Full Consolidation |
| Heumann Pharma Gmbh & Co. Generica KG | 100.00% | Full Consolidation |
| Torrent Australasia Pty Limited | 100.00% | Full Consolidation |
| Torrent Pharma S.R.L | 100.00% | Full Consolidation |
| Laboratorios Torrent S.A. De C.V. | 100.00% | Full Consolidation |
| Heunet Pharma Gmbh | 100.00% | Full Consolidation |
| Norispharm Gmbh | 100.00% | Full Consolidation |
| Torrent Pharma (Thailand) Co. Limited | 100.00% | Full Consolidation |
| Torrent Pharma (UK) Limited | 100.00% | Full Consolidation |
| Laboratories Torrent (Malaysia) SDN.BHD | 100.00% | Full Consolidation |
| Torrent Pharma France S.A.S. | 100.00% | Full Consolidation |
| Aptil Pharma Limited | 100.00% | Full Consolidation |

*Source: Company*

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ICRA Limited was set up in 1991 by leading financial/investment institutions, commercial banks and financial services companies as an independent and professional investment Information and Credit Rating Agency.

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