Shilpa Medicare Limited (SML) reported weak performance for Q3FY2021 with results coming in below estimates. Operations at the Jadcherla plant were impacted due to warning letter receipt as well as upgradation, leading to delay/temporary stoppage of production. Sales for the quarter stood at Rs. 191.2 crore, down 19% y-o-y and were below estimates. Operating profit margin (OPM) fell to 11% as compared to 31% in Q3FY2020, driven by contraction in gross margin and operating de-leverage. Tracking the operating performance and a higher interest cost, PAT at Rs. 7.7 crore declined by 86% y-o-y and missed estimates. Going ahead SML’s growth prospects are healthy and the performance is expected to improve. SML’s API segment offers a healthy growth outlook. The API segment, which accounts for around half of the company’s revenue, is standing strong. An array of opportunities lies ahead for this segment, including the dual sourcing mandates from global players. This is complemented by expanded capacities with key regulatory approvals in place and a strong product pipeline, which would unfold going ahead. SML plans to commercialize 3-4 molecules per year in the API segment. The formulations business is also expected to grow at a steady pace, backed by growth in the base business and new product pipeline. Impact in the US business due to receipt of the warning letter is likely to be offset by growth in other areas/geographies - entry in new areas and increasing geographic reach – expansion in Europe and RoW markets, foray into domestic oncology formulations, and niche over-the-counter (OTC) markets. We believe SML’s strategy of building a high-value oncology pipeline for regulated markets and foray into biosimilars/biologics, coupled with focus to pursue opportunities in CDMO & Vaccines space would play out well and support growth.

Key positives
- API segment revenues grew by a healthy 6.7% yoy for the quarter.
- SML has completed de bottlenecks of the oncology block and has started commercial production.

Key negatives
- The formulations segment’s revenue almost halved on a y-o-y basis due to impact of the warning letter and remediation actions undertaken leading to delay/temporary stoppages in production.
- OPM contracted to 11% in Q3FY2021 versus 31% in Q3FY2020, led by 630 bps decline in gross margin and operating de-leverage.

Our Call
Valuation: Retain Buy with a revised PT of Rs. 520: SML reported a weak performance for the quarter, however the growth prospects are healthy and the performance is expected to improve. SML’s API business, which constitutes around half of its overall revenue, has a strong growth outlook. Expansion and upgradation of the API facilities (including oncology blocks) and plans to commercialise 3-4 molecules per year, which is likely to sustain going ahead backed by healthy product filling pipeline, could drive the growth of API segment. Focus on building presence in domestic formulations market, new product pipeline coupled with expansion into new geographies (non US markets) and markets would be key growth drivers for the formulations segment. Moreover, SML is evaluating opportunities/pursuing partnerships in the CDMO and vaccines space and expects these opportunities to drive growth going ahead, though clarity on timelines is awaited. SML’s Q3FY2021 performance was weak and results missed estimates. Factoring in these, we have revised downwards our estimates for FY2022/2023. At the CMP, the stock is trading at 14.9x its FY2022E/2023E EPS. Better growth prospects, strong financials, and improving return ratios are key positives. Resolution of the warning letter for Jadcherla plant is crucial from growth perspective and upon resolution can result in earnings upgrades. We retain our Buy recommendation on the stock with a revised PT of Rs. 520.

Key risk
Any adverse change in the regulatory landscape can impact earnings prospects.

Valuations

<table>
<thead>
<tr>
<th></th>
<th>Rs cr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Sales</td>
<td>733.4</td>
</tr>
<tr>
<td>EBITDA</td>
<td>169.6</td>
</tr>
<tr>
<td>OPM (%)</td>
<td>21.2</td>
</tr>
<tr>
<td>Reported PAT</td>
<td>92.4</td>
</tr>
<tr>
<td>EPS (Rs)</td>
<td>11.3</td>
</tr>
<tr>
<td>PER (x)</td>
<td>37.9</td>
</tr>
<tr>
<td>EV/EBITDA (x)</td>
<td>21.0</td>
</tr>
<tr>
<td>P/BV (x)</td>
<td>2.9</td>
</tr>
<tr>
<td>ROCE (%)</td>
<td>8.8</td>
</tr>
<tr>
<td>RONW (%)</td>
<td>9.4</td>
</tr>
</tbody>
</table>

Source: Company; Sharekhan estimates
**Weak Quarter:** Q3FY2021 was a weak quarter for SML with results missing estimates. Operations at the Jadcherla plant were impacted as the company resorted to remediation actions as well as upgradation leading to delay/temporary stoppage of production. Sales for the quarter stood at Rs. 191.2 crore, down 19% y-o-y and below estimates. The formulations segment’s revenue almost halved y-o-y to Rs. 34.2 crore versus Rs. 64.8 crore in Q3FY2020, while the API segment’s sales were up 7% y-o-y. OPM fell to 11% in Q3FY2021 as compared to 31% in Q3FY2020 and was significantly below estimates. Gross margin also shrank sharply by 630 bps y-o-y, while employee cost and other expenses (as a % of sales) expanded by 1070 bps and 310 bps y-o-y, respectively, pointing at operating de-leverage playing out. Operating profit at Rs. 21 crore was down 71.6% y-o-y. Interest cost for the quarter stood at Rs. 4.8 crore as compared to Rs. 1.3 crore in Q3FY2020. Therefore, tracking a weak operating performance and a high interest cost, PAT for the quarter stood at Rs. 7.7 crore, down 86% y-o-y and was substantially below estimates.

**Sturdy growth in the API segment to sustain:** SML’s API business is comparatively better placed than the formulations segment. Sales from the segment has reported healthy growth of 7% y-o-y to Rs. 127.83 crore. Going ahead, outlook for the API segment is healthy and this augurs well from the growth perspective. SML looks to commercialise 3-4 molecules every year going ahead in the API segment, while two of its products are already under the review with WHO and the approval for the same is expected by March 2021. Moreover, the company has completed de-bottlenecking of its oncology blocks and has commenced commercial manufacturing from the same. Simultaneously, it has initiated de-bottlenecking at the other two oncology blocks. Based on the recent expansion and upgradation of its oncology API’s facilities, SML has added sizeable capacities to the above-mentioned facilities. SML is further focusing its efforts to debottleneck the oncology block so as to enhance capacity. De-bottlenecking initiatives would provide ample visibility going ahead on growth.

**Formulations Q3FY2021 performance impacted due to remediation actions, expect improvement ahead:** SML’s formulations segment’s revenue for Q3FY2021 almost halved to Rs. 34.26 crore as compared to Rs. 64.86 crore in Q3FY2020. The decline in revenue from the segment can be attributed to warning letter received from the USFDA and the commitments given by the company for remediation actions given by the company, which resulted in delayed/temporary stopping of commercial production from the plant. Going ahead, the outlook looks positive and the company sees growth to come in from geographies other than the US. In Europe, SML has a strong product pipeline, which is reflected in 21 fillings done, of which it has received 13 approvals, while eight product approvals are awaited. The company has also filed for one product in Canada and the approval for the same is awaited. With respect to US markets as well, SML has a total of 43 products filed, of which it has received approvals for 25 products, while it is awaiting approvals for 18 products. Moreover, SML has filed for around 166 patents in the formulations space and has been granted patents for 15 of its fillings, while the balance are pending approval. This points at a possibly healthy product pipeline, which could unfold going ahead and support growth. Moreover, in Q3FY2021, SML has done four product commercialisation in the formulations space, which include - Axitinib and variants of green T films (commercialised in domestic markets) and has commercialised Azacitidine injectable for two customers in Europe from Jadcherla plants. Collectively, a healthy product line up, focus on non-US markets for growth, and new product launches would fuel growth of the formulations segment ahead. However, SML’s Jadcherla plant is under USFDA warning letter and the company is engaged with a third party consultant for resolution of the same. A successful resolution of the USFDA warning letter for Jadcherla plant is crucial from a growth perspective.
Formulations product pipeline as of December 2020

<table>
<thead>
<tr>
<th>Patents</th>
<th>Filings</th>
<th>Approved</th>
<th>Pending</th>
</tr>
</thead>
<tbody>
<tr>
<td>US ANDA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>By SML</td>
<td>23</td>
<td>13</td>
<td>12</td>
</tr>
<tr>
<td>By Customers</td>
<td>18</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>US NDA</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Total (US)</td>
<td>43</td>
<td>25</td>
<td>18</td>
</tr>
<tr>
<td>EU Filings</td>
<td>21</td>
<td>13</td>
<td>8</td>
</tr>
<tr>
<td>Canada</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total (US+EU)</td>
<td>65</td>
<td>38</td>
<td>27</td>
</tr>
</tbody>
</table>

Source: Company; Sharekhan Research

Healthy growth outlook backed by strong dossier fillings and CDMO opportunities: Post the receipt of warning letter from the USFDA for the Jadcherla formulations plant, the company has been focusing on resolution of the same and is committed to faster resolution. Further, outlook for the API segment, which constitutes around 55% of FY2020 sales, is strong, backed by a sturdy new product pipeline. As of December 2020, SML has a total of 203 dossiers filed across the RoW markets, such as Asia, LATAM, MENA, and African regions largely. Of the 203 dossiers being filed, the company has approval for 42, while the balance 139 are under review. This points at a strong product pipeline, which in turn would drive the performance ahead. On the formulations segment, markets other than the US are expected to drive growth, especially RoW markets. Moreover, the company is considering diversification in other therapeutic areas such as biologics, portfolio expansion to transdermal dosage forms, and oral thin films formulations. In India, the company has launched its own branded products for the ODF segment. Further, the company has laid focus on strengthening its marketing team in the respective geographies, which would enable it to grow. SML is also pursuing partnership opportunities in the vaccine space (recombinant, viral vaccines) as well as is looking for emerging opportunities in the CDMO space. However, further clarity on the timelines for the vaccine as well as CDMO opportunities are unclear, though these could be the drivers for the company in the long run.

Results

<table>
<thead>
<tr>
<th>Particulars</th>
<th>Q3FY2021</th>
<th>Q3FY2020</th>
<th>YoY %</th>
<th>Q2FY2021</th>
<th>QoQ %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Income</td>
<td>191.2</td>
<td>236.9</td>
<td>-19.3</td>
<td>278.9</td>
<td>-31.4</td>
</tr>
<tr>
<td>Expenditure</td>
<td>170.3</td>
<td>163.1</td>
<td>4.4</td>
<td>210.3</td>
<td>-19.0</td>
</tr>
<tr>
<td>Operating profit</td>
<td>21.0</td>
<td>73.7</td>
<td>-71.6</td>
<td>68.7</td>
<td>-69.5</td>
</tr>
<tr>
<td>Other income</td>
<td>8.6</td>
<td>3.3</td>
<td>164.5</td>
<td>9.2</td>
<td>-6.5</td>
</tr>
<tr>
<td>EBITDA</td>
<td>29.6</td>
<td>77.0</td>
<td>-61.6</td>
<td>77.9</td>
<td>-62.0</td>
</tr>
<tr>
<td>Interest</td>
<td>4.8</td>
<td>1.3</td>
<td>278.3</td>
<td>4.0</td>
<td>21.5</td>
</tr>
<tr>
<td>Depreciation</td>
<td>13.7</td>
<td>11.0</td>
<td>25.1</td>
<td>12.7</td>
<td>8.1</td>
</tr>
<tr>
<td>PBT</td>
<td>11.1</td>
<td>64.8</td>
<td>-82.9</td>
<td>61.2</td>
<td>-82.0</td>
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<tr>
<td>Tax</td>
<td>2.9</td>
<td>10.5</td>
<td>-72.3</td>
<td>16.0</td>
<td>-81.8</td>
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<tr>
<td>Reported PAT</td>
<td>7.7</td>
<td>55.1</td>
<td>-86.1</td>
<td>45.4</td>
<td>-83.1</td>
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<tr>
<td>Margins</td>
<td></td>
<td></td>
<td></td>
<td>BPS</td>
<td>BPS</td>
</tr>
<tr>
<td>OPM (%)</td>
<td>11.0</td>
<td>31.1</td>
<td>-2016.9</td>
<td>24.6</td>
<td>-1365.9</td>
</tr>
</tbody>
</table>

Source: Company; Sharekhan Research
Outlook and Valuation

■ Sector View – Growth momentum to improve

Indian pharmaceutical companies are better placed to harness opportunities and post healthy growth going ahead. Indian companies are among the most competitive ones globally and hold a sizeable market share in most developed as well as other markets. Moreover, other factors such as easing of pricing pressures (especially in the US generics market), rise in product approvals, and plant resolutions by the USFDA coupled with strong growth prospects in domestic markets and emerging opportunities in the API space would be key growth drivers. This would be complemented by strong capabilities developed by Indian companies (leading to a shift towards complex molecules and biosimilars) and commissioning of expanded capacities by select players over the medium term. Collectively, this points towards a strong growth potential going ahead for pharma companies.

■ Company Outlook – Improving growth prospects

The API segment, which accounts for around half of the company’s revenue, is standing strong. An array of opportunities lies ahead for this segment, including dual sourcing mandates from global players. This is complemented by expanded capacities with key regulatory approvals in place and a strong product pipeline, which would unfold going ahead. The formulations business is also expected to grow at a steady pace. Erosion in the US business due to receipt of the warning letter is likely to be offset by growth in other areas/geographies - entry into new areas of oncology/OTC products and increasing its geographic reach. SML has also stepped into the biopharmaceutical space, with products offering substantial market opportunities, although the benefits are likely to accrue by the end of FY2022. We believe SML’s strategy of building a high-value oncology pipeline for regulated markets and foray into biosimilars/biologics would play out well and support growth. This would be complemented by efforts to pursue opportunities in CDMO as well as vaccines, though the benefits could accrue in the medium to long term.

■ Valuation – Retain Buy with a revised PT of Rs. 520

SML reported a weak performance for the quarter, however the growth prospects are healthy and the performance is expected to improve. SML’s API business, which constitutes around half of its overall revenue, has a strong growth outlook. Expansion and upgradation of the API facilities (including oncology blocks) and plans to commercialise 3-4 molecules per year, which is likely to sustain going ahead backed by strong healthy product filling pipeline, could support growth of the API segment. Focus on building presence in domestic formulations markets, new product pipeline coupled with expansion into new geographies (non US markets) and markets would be key growth drivers for the formulations segment. Moreover, SML is evaluating opportunities/pursuing partnerships in the CDMO and vaccines space and expects these opportunities to drive growth going ahead, though clarity on timelines is awaited. SML’s Q3FY2021 performance was weak and results missed estimates. Factoring in these, we have revised downwards our estimates for FY2022/FY2023. At the CMP, the stock is trading at 18.1x and 14.9x its FY2022E/FY2023E EPS. Better growth prospects, strong financials, and improving return ratios are key positives. Resolution of the warning letter for Jadcherla plant is crucial from growth perspective and upon resolution can result in earnings upgrades. We retain our Buy recommendation on the stock with a revised PT of Rs. 520.

One-year forward P/E (x) band

Peer valuation

<table>
<thead>
<tr>
<th>Particulars</th>
<th>CMP (Rs / Share)</th>
<th>O/S Shares (Cr)</th>
<th>MCAP (Rs Cr)</th>
<th>P/E (x) FY20</th>
<th>P/E (x) FY21E</th>
<th>P/E (x) FY22E</th>
<th>EV/EBIDTA (x) FY20</th>
<th>EV/EBIDTA (x) FY21E</th>
<th>EV/EBIDTA (x) FY22E</th>
<th>RoE (%) FY20</th>
<th>RoE (%) FY21E</th>
<th>RoE (%) FY22E</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shilpa Medicare</td>
<td>430.0</td>
<td>8.2</td>
<td>3,503.0</td>
<td>22.3</td>
<td>23.6</td>
<td>18.1</td>
<td>15.9</td>
<td>15.0</td>
<td>11.5</td>
<td>11.8</td>
<td>10.2</td>
<td>11.8</td>
</tr>
<tr>
<td>Laurus Labs</td>
<td>376.0</td>
<td>53.2</td>
<td>20,155.0</td>
<td>78.4</td>
<td>217.0</td>
<td>18.4</td>
<td>37.2</td>
<td>14.8</td>
<td>12.5</td>
<td>14.4</td>
<td>34.2</td>
<td>28.8</td>
</tr>
<tr>
<td>Strides Pharma Sciences</td>
<td>889</td>
<td>9</td>
<td>7969</td>
<td>56.9</td>
<td>30.4</td>
<td>19.9</td>
<td>15.1</td>
<td>12.4</td>
<td>9.8</td>
<td>1.7</td>
<td>11.1</td>
<td>12.8</td>
</tr>
</tbody>
</table>

Source: Sharekhan Research

Source: Company, Sharekhan estimates
About company
SML was incorporated in 1987 at Raichur, Karnataka, India. SML is one of the leading API and formulations manufacturers with strong capabilities in the therapeutic area of oncology. The company is also present in the non-oncology therapy areas and has recently forayed into formulations, biologics, oral dissolving films, and transdermal patches. SML supplies more than 30 oncology APIs, including key products such as Capecitabine, Gemcitabine Hydrochloride, Axitinib, Erlotinib Hydrochloride, and Irinotecan Hydrochloride for various regulated markets, including US, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets. The company also derives a small part of its revenue from sale of non-oncology APIs, with key products being Ambroxol (Mucolytic agent) in Europe and Tranexamic Acid and Ursodeoxycholic Acid in India. SML operates five manufacturing units, four of them being in India and one in Austria. SML's product range includes over 44 oncology and non-oncology APIs. The company's formulation product range consists of 16 injectable dosage forms, 19 oral solid dosage forms under SML, and 13 formulations under SML's wholly owned subsidiary Shilpa Therapeutics Private Limited. With respect to geographical mix, India accounts for 32.5% of FY2020 sales. While the US, Europe, and RoW markets constitute 21.3%, 22.2%, and 24%, respectively.

Investment theme
SML has an established presence in APIs and is an emerging player in formulations. The API segment, which accounts for around half of the company’s revenue, is standing strong. An array of opportunities lies ahead for SML’s API segment, including the dual sourcing mandates from global players. This is complemented by expanded capacities with key regulatory approvals in place and a strong product pipeline, which would unfold going ahead. The formulations segment is also gaining traction, backed by a sturdy product pipeline and increasing geographic reach. The share of formulations in total sales has increased meaningfully and is set to increase over the next two years. A shift in sales mix in favour of the high-margin formulations segment augurs well for the company as it would push the company in a high-growth trajectory. SML has also recently acquired a research-focused drug development company, which is expected to strengthen its R&D capabilities. We believe SML's strategy of building a high-value oncology pipeline for regulated markets and foray into biosimilars/biologics would play out well and support growth. This would be complemented by efforts to pursue opportunities in CDMO as well as vaccines, though the benefits could accrue in the medium to long term.

Key Risks
Any adverse change in the regulatory landscape can impact earnings prospects.

Additional Data
Key management personnel

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omprakash Inani</td>
<td>Chairman</td>
</tr>
<tr>
<td>Mr. Vishnukant Chaturbhuj Bhutada</td>
<td>Managing Director</td>
</tr>
<tr>
<td>Mr. Sharath Reddy</td>
<td>Whole time Director</td>
</tr>
<tr>
<td>Mr. Amit Chander</td>
<td>Independent Director</td>
</tr>
</tbody>
</table>

Source: Company Website

Top shareholders

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Holder Name</th>
<th>Holding (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>BARCLAYS MERCHANT BANK (SINGAPORE) LIMITED - ODI</td>
<td>1.98</td>
</tr>
<tr>
<td>2</td>
<td>BARING INDIA PRIVATE EQUITY FUND III LISTED INVEST</td>
<td>1.36</td>
</tr>
<tr>
<td>3</td>
<td>TA FI INVESTORS LIMITED</td>
<td>3.71</td>
</tr>
<tr>
<td>4</td>
<td>TANO MAURTIUS INDIA FVCI II</td>
<td>7.58</td>
</tr>
<tr>
<td>5</td>
<td>DURO ONE INVESTMENTS LIMITED</td>
<td>1.42</td>
</tr>
<tr>
<td>6</td>
<td>PIVOTAL ENTERPRISES PRIVATE LIMITED</td>
<td>2.91</td>
</tr>
<tr>
<td>7</td>
<td>PIVOTAL BUSINESS MANAGERS LLP</td>
<td>1.09</td>
</tr>
<tr>
<td>8</td>
<td>CLSA GLOBAL MARKETS PTE. LTD.</td>
<td>0.98</td>
</tr>
</tbody>
</table>

Source: Bloomberg

Sharekhan Limited, its analyst or dependant(s) of the analyst might be holding or having a position in the companies mentioned in the article.
**Understanding the Sharekhan 3R Matrix**

### Right Sector

<table>
<thead>
<tr>
<th>Positive</th>
<th>Strong industry fundamentals (favorable demand-supply scenario, consistent industry growth), increasing investments, higher entry barrier, and favorable government policies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutral</td>
<td>Stagnancy in the industry growth due to macro factors and lower incremental investments by Government/private companies</td>
</tr>
<tr>
<td>Negative</td>
<td>Unable to recover from low in the stable economic environment, adverse government policies affecting the business fundamentals and global challenges (currency headwinds and unfavorable policies implemented by global industrial institutions) and any significant increase in commodity prices affecting profitability.</td>
</tr>
</tbody>
</table>

### Right Quality

<table>
<thead>
<tr>
<th>Positive</th>
<th>Sector leader, Strong management bandwidth, Strong financial track-record, Healthy Balance sheet/cash flows, differentiated product/service portfolio and Good corporate governance.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutral</td>
<td>Macro slowdown affecting near term growth profile, Untoward events such as natural calamities resulting in near term uncertainty, Company specific events such as factory shutdown, lack of positive triggers/events in near term, raw material price movement turning unfavourable</td>
</tr>
<tr>
<td>Negative</td>
<td>Weakening growth trend led by led by external/internal factors, reshuffling of key management personal, questionable corporate governance, high commodity prices/weak realisation environment resulting in margin pressure and deteriorating balance sheet</td>
</tr>
</tbody>
</table>

### Right Valuation

<table>
<thead>
<tr>
<th>Positive</th>
<th>Strong earnings growth expectation and improving return ratios but valuations are trading at discount to industry leaders/historical average multiples, Expansion in valuation multiple due to expected outperformance amongst its peers and Industry up-cycle with conducive business environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neutral</td>
<td>Trading at par to historical valuations and having limited scope of expansion in valuation multiples.</td>
</tr>
<tr>
<td>Negative</td>
<td>Trading at premium valuations but earnings outlook are weak; Emergence of roadblocks such as corporate governance issue, adverse government policies and bleak global macro environment etc warranting for lower than historical valuation multiple.</td>
</tr>
</tbody>
</table>

Source: Sharekhan Research
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