九洲药业 Zhejiang Jiuzhou Pharmaceutical (603456 CH)

诺欣妥专利诉讼对短期业绩增长确定性风险较小
Entresto® Combination Patent Litigation Poses Litttle Certainty Risk to Short-Term Performance Growth

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热点速评 Flash Analysis

(Please see APPENDIX 1 for English summary)

事件

2023 年 7 月 7 日，美国特拉华州地区法院裁定 Entresto（sacubitril/valsartan）“组合专利”（美国专利号：8,101,659）无效。诺华表示将继续向联邦巡回上诉法院提起上诉，以维持诺欣妥组合专利的有效性。同时公司还披露了 Entresto 在美国登记的多项专利，其中包括组合专利、无定形专利，以及 2 个晶型专利和 1 个剂量方案专利，这些专利将于 2023 年至 2036 年间到期（包括儿科适应症延长）。

点评

（1）**专利纠纷上诉期间，我们认为，诺欣妥被商业化仿制生产的风险较小。**由于诺华在专利期内已经提出了上诉，我们认为，按照制药行业专利纠纷诉讼的惯例，专利纠纷诉讼通常要持续两到三年时间。因此，我们认为，在法院最终判决结果之前，第三方对诺欣妥进行仿制生产的可能性较小。

（2）核心生产专利仍在专利保护期，其他厂商难以绕开相关专利。诺华围绕“诺欣妥”进行了充分的专利布局保护，其他企业想要进行仿制生产需要面对的诸多专利壁垒。在美国，诺欣妥拥有保护其配方的多项专利，除组合专利（2025/7/15 到期）外，还包括无定形专利（2026/11/8 到期）、晶型专利（2027/5/8 和 2027/11/27 到期）、剂量方案专利（2036/5/9 到期），此次被美国地区法院裁定无效的组合专利仅为其中之一，其关键的晶型等生产专利到期以前，其他厂商无法绕过专利进行生产。

（3）明年订单仍保持增长趋势，我们认为短期业绩增长依托诺华订单的确定性较强，长期通过 CDMO 客户不断拓展，增长趋势向好。2022 年公司 CDMO 订单共承接项目 851 个（+30.7%），其中上市项目 26 个（+30%），III 期项目 61 个（+24.5%），公司新增商业化品种 6 个、临床三期项目 12 个，主要涉及抗肿瘤、中枢神经脂肪肝等领域，从现有项目储备和客户预测来看，我们认为 2023 年商业化品种有望继续保持一定增长。2019 年，九洲药业收购了美国 CRO 公司即瑞博美国，迈出了公司 CDMO 业务国际化的重要一步。2022 年公司增资瑞博美国，新增研发人员和研发设备，扩建中试车间（已投入使用），进一步拓展了美国业务承接能力，加快海外商业化生产基地布局，实现海外创新药 CDMO 一站式服务，中长期规划推动 CGT 与大分子业务布局。根据 2022 年报，除 Novartis 外，公司与国际知名药企 Roche、Zoetis、Gliead、第一三共等也形成深度合作，我们认为未来业务订单有望实现快速增长，公司长期业绩趋势较好。

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APPENDIX 1

Summary

Event

On July 07, 2023, the U.S. District Court for the District of Delaware issued a negative decision regarding the validity of a patent covering Entresto and combinations of sacubitril and valsartan, which expires in 2025 with its pediatric exclusivity. Novartis strongly believes the combination patent is valid and will appeal to the U.S. Court of Appeals for the Federal Circuit (CAFC) to reverse the District Court's decision. Meanwhile, Novartis also disclosed multiple patents of Entresto registered in the United States, including combination therapy patents, amorphous patents, as well as 2 crystalline patents and 1 dosage regimen patent, which will expire between 2023 and 2036 (including extension of pediatric indications)

Flash Analysis

(1) During the appeal period of the patent dispute, we believe that the risk of Entresto being imitated produced commerically is relatively low. According to the practice in the pharmaceutical industry, patent dispute litigation usually lasts for two to three years. Since Novartis has already filed an appeal during the patent period, we believe that there is less possibility for a third party to replicate the production of Entresto before the final judgment of the court.

(2) The core production patents are still under protection, making it difficult for other manufacturers to bypass related patents. Novartis has provided sufficient patent layout protection around Entresto, and other enterprises need to face many patent barriers in order to carry out imitation production. In the United States, Entresto has multiple patents protecting its formula, including combination therapy patents (expiring on July 15, 2025), amorphous patents (expiring on November 8, 2026), crystalline patents (expiring on May 8, 2027 and November 27, 2027), and dosage regimen patents (expiring on May 9, 2036). The combination therapy patents that were ruled invalid by the US District Court this time are only one of them. Before the expiration of its key crystalline and other production patents, other manufacturers are unable to bypass the patents for production.

(3) In 2023, orders will continue to grow, and we believe that the short-term performance growth will rely on the strong certainty of Novartis' orders. In the long term, the company will continue to expand CDMO customers, and the growth trend will be positive. In 2022, the company's CDMO orders took on a total of 851 projects (+30.7%), including 26 listed projects (+30%) and 61 Phase III projects (+24.5%). The company added 6 commercial varieties and 12 clinical phase III projects, mainly involving fields such as anti-cancer and treatment of fatty liver causing CNS damage. Based on current reserved projects and customer forecasts, we believe that commercial varieties are expected to maintain a continuous growth in 2023. In 2019, Jiuzhou Pharmaceutical acquired an American CRO company, Raybow America, taking an important step towards the internationalization of the company's CDMO business. In 2022, the company increased its investment in Raybow America, added R&D personnel and equipment, expanded the pilot plant (which has already been put into use), further expanded its business capacity in the United States, accelerated the layout of overseas commercial production bases, achieved one-stop services for overseas innovative drug CDMO, and promoted the layout of CGT and macromolecular business in medium and long-term planning. According to the 2022 annual report, in addition to Novartis, the company has also formed deep cooperation with international well-known pharmaceutical enterprises such as Roche, Zoetis, Gliead, Daiichi Sankyo, etc. We believe that business orders are expected to achieve rapid growth in the future, and the company's long-term performance trend is relatively good.

Risk

The outcome of the patent lawsuit against Entresto did not meet expectations, global biopharmaceutical research and development expenses declined, competition in the small molecule CDMO industry intensified, customer product sales did not meet expectations, and overseas business customer expansion did not meet expectations.

附录 APPENDIX

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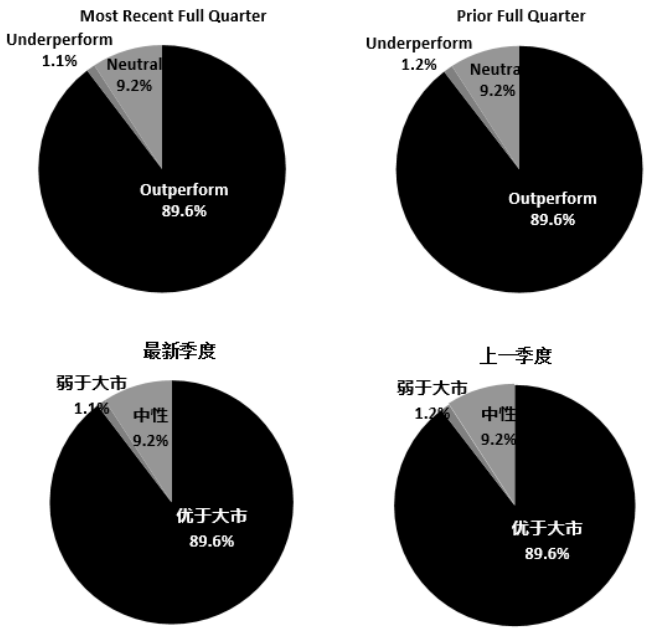

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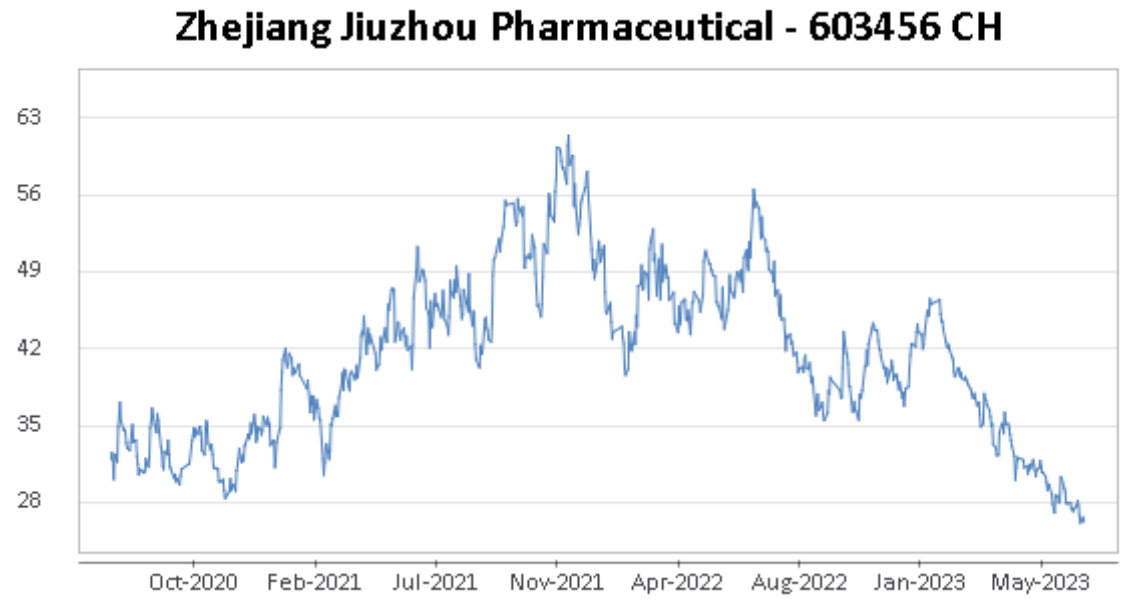
Recommendation Chart



Source: Company data Bloomberg, HTI estimates