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Overview

ScinoPharm at a Glance

- Est. in 1997 and HQ in Taiwan (Tainan) with cGMP plants/R&D in Taiwan and China (Changshu) and marketing forces in Taiwan and China (Shanghai)
- Specializing in high potency (steroid/cytotoxic) APIs and injectable formulation, serving customers worldwide
- 70 generic APIs in portfolio with 29 APIs approved
  - 60 active US DMFs (805 DMFs WW) with 31 of them oncology APIs
- 100+ contract projects with 6 launched (4 NCEs) and 7 in phase 3 for NDA filing in 1-3 years
- Certified by key international regulators - US FDA, EMA, EDQM, Australian TGA, Japanese PMDA, Korea KFDA, Mexico COFEPRIS and German Authority

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World Class Facilities

Taiwan

■ API Plant

- 6 of 16 production lines equipped with high potency capabilities for cytotoxic/steroid
- Provides comprehensive CRAM services for brand drug companies

■ Injectable Plant

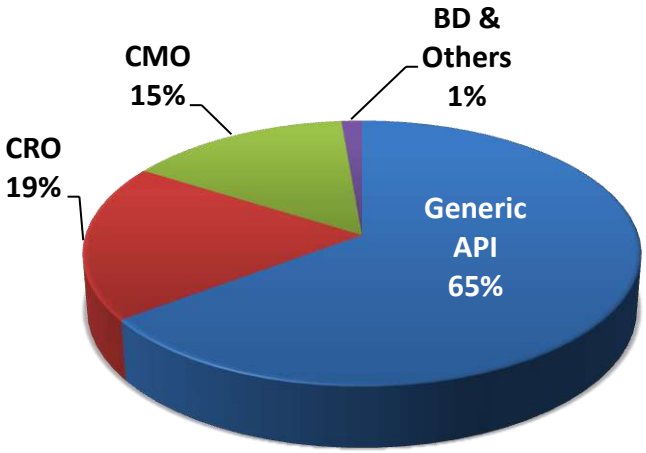
- Vial and cartridge production lines for oncological and peptide products
- To meet US, EU, Japan GMP standards by adopting state-of-the-art isolator technology and single use technology for product contact path

China

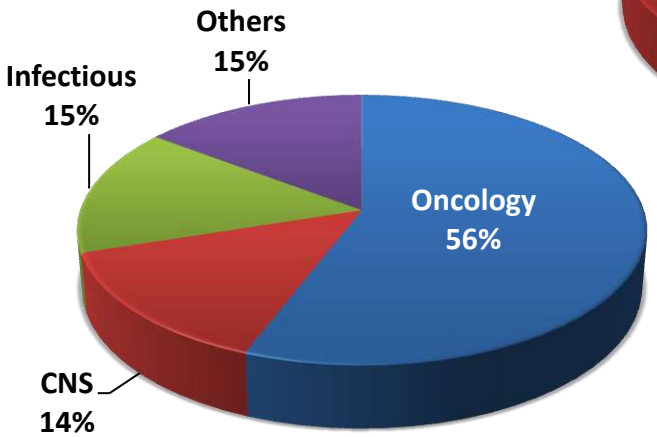
■ API Plant

- 3 of 7 production lines equipped with high potency capabilities for cytotoxic
- US FDA approved cGMP facility for intermediates & high potency API
- Strong R&D capabilities of APIs on small to large scales for generic & CRAM markets
- Strategic partnerships with China clients for formulations targeting global/China markets

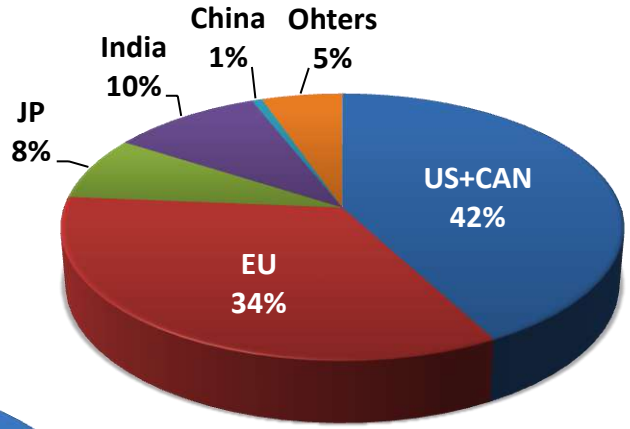
2018 Sales Distribution



by Business



by Indication



by Region

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Regulatory Inspections (API)

- US FDA inspection (6)
  - 2001/10; 2005/08; 2008/10; 2012/03; 2015/03; 2017/02
- Europe EMA inspection (2)
  - 2013/01; 2014/03
- Japan PMDA inspection (30)
  - On-site inspection (2) on 2008/05 and 2017/11
  - Desk inspection (28)
- EDQM Inspection (1)
  - 2016/10
- Taiwan DOH / TFDA inspection (22)
  - 2002/01; 2003/01; 2003/06; 2004/04; 2005/11; 2007/12; 2008/02; 2008/10; 2009/02; 2010/04; 2010/11; 2011/09; 2012/01; 2012/03; 2012/12; 2013/04; 2013/10; 2014/01; 2015/05; 2016/02; 2016/03;2016/06; 2017/01
- German authority HSSEN (1)
  - 2016/11
- Korea KFDA inspection (5)
  - 2008/08; 2011/02; 2015/09
  - Desk inspection (2)
- Mexico COFEPRIS inspection (4)
  - 2010/10; 2013/05; 2016/01; 2017/09

Strategies

Strategies

- Optimize Existing Generic API Portfolio
- Value up into Injectables
- Expand CDMO Business
- Actively Develop Japan and Emerging Markets

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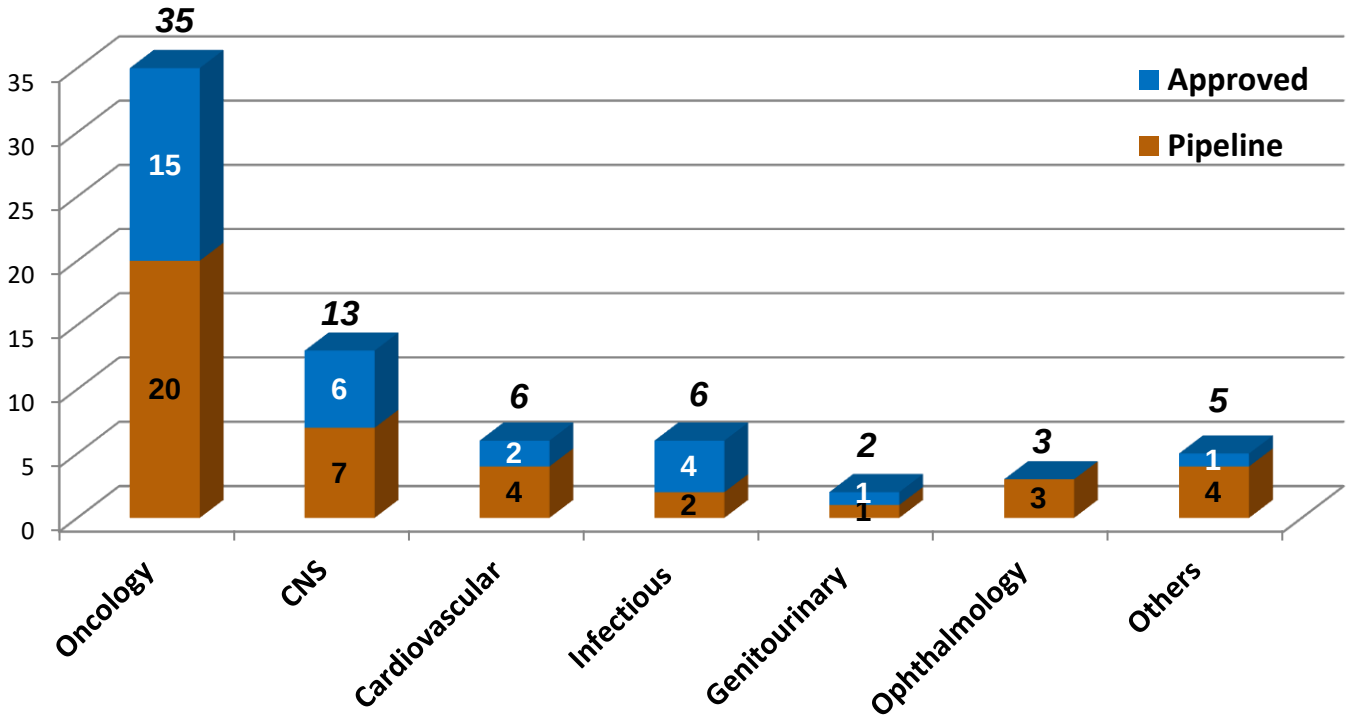
Strategy - Optimize Existing Generics API Portfolio



Note: Others (Women's Health, Respiratory, Gastrointestinal, Immunology and Metabolic)

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Strategy - Value Up into Injectables

- Leverage leading position in oncology APIs to expand formulation portfolio
- Target complex products with high entry barriers or high unit-pricing
- Develop dossiers based on API expertise, including ANDA filing
  - Apply ANDA with in-house APIs via P4 or 505(b)(2) fast track
  - 3 US ANDA filings (via Injectable CMO) with 2 approvals (Decitabine and Fondaparinux Sodium)
  - Submission of 1st in-house ANDA in late 2019
- 15 projects with multiple partners in China and US/EU

In-House Injectable Portfolio

Vial Product Line Cytotoxic Injectable	Liquid Solution **3**	Lyophilized Powder **6**
Cartridge Product Line Peptide Injectable	Prefilled-Syringe **2**	Pen Device **2**

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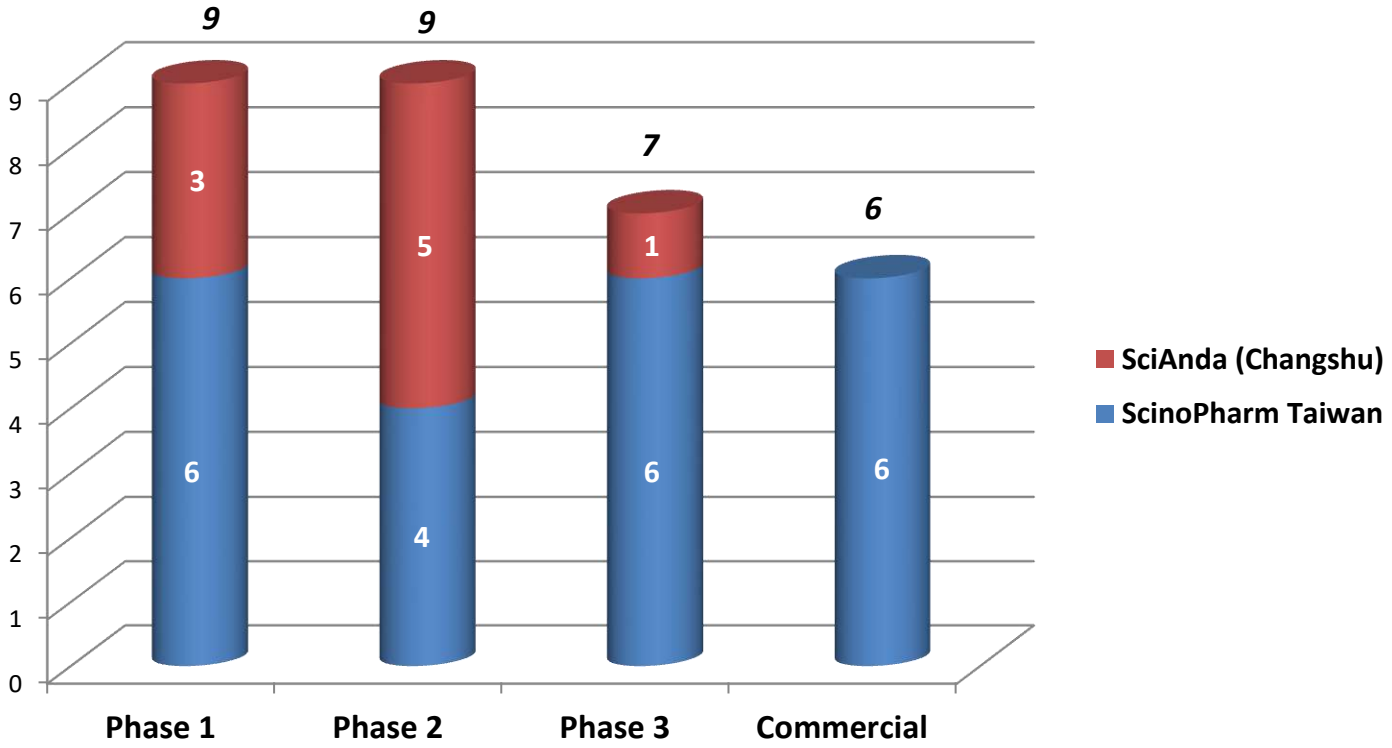
Strategy - Expand CDMO Business



Strategy - Develop Japan and Emerging Markets

Japan

- 20 generic customers with 7 from top 10 drug firms
- Direct business with local generic customers
- Support Japanese and foreign pharmaceutical companies for market expansion
- Develop CRAM projects and leverage new capabilities of injectables

China

- Focus on mid- to late-phase CRO projects
- Seek generic APIs/intermediates with large demand

South America & Russia

- Focus on oncology API/injectable market development

Brand Quality with Asian Advantages

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