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Key Credit Factors For The Pharmaceutical Industry

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Key Credit Factors For The Pharmaceutical Industry

*(**Editor's Note:** These criteria supersede "Key Credit Factors: Business And Financial Risks In The Global Pharmaceutical Industry," Jan. 22, 2009.)*

1. Standard & Poor's Ratings Services is refining and adapting its methodology and assumptions for rating pharmaceutical companies. We are publishing this article to help market participants better understand the key credit factors in this industry. These criteria are related to our criteria article "Principles Of Credit Ratings," published on Feb. 16, 2011, as well as our global corporate criteria (see "Corporate Methodology," published Nov. 19, 2013).
2. These criteria supersede “Key Credit Factors: Business And Financial Risks In The Global Pharmaceutical Industry,” Jan. 22, 2009.

SCOPE OF THE CRITERIA

3. These criteria apply to ratings on issuers in the global prescription pharmaceutical industry, including companies that develop, manufacture, or market branded pharmaceuticals or generic drugs (low-cost replicas of branded patent-protected drugs), and contract drug manufacturers (CMOs).
4. These criteria do not apply to contract research organizations (see "Key Credit Factors For The Business And Consumer Services Industry," published Nov. 19, 2013) and companies that develop, manufacture, and market over-the-counter (OTC) pharmaceuticals (see “Key Credit Factors For The Branded Nondurables Industry,” published Nov. 19, 2013).

SUMMARY OF CRITERIA UPDATE

5. We are updating our criteria for analyzing pharmaceutical companies, applying our global corporate criteria. We view pharmaceuticals as a "low risk" industry under our criteria, given its "low risk" cyclicality and "low risk" degree of competitive risk and growth environment. Our pharmaceutical industry risk assessment encompasses both branded and generic drug-makers, as well as CMOs. Differences among the three subsectors are addressed in our competitive position analysis.
6. In assessing the competitive position of a branded pharmaceutical company we put particular emphasis on: its ability to replace profits from branded drugs when market exclusivity ends (typically when patents expire), including the late-stage product development portfolio; and product and therapeutic diversity. For a generic drug company, speed-to-market is key and manufacturing expertise is also important. For a CMO, we focus on efficient manufacturing and technical capabilities.

IMPACT ON OUTSTANDING RATINGS

7. We do not expect these criteria, in and of themselves, to result in any rating changes.

EFFECTIVE DATE AND TRANSITION

8. These criteria are effective immediately upon publication.

METHODOLOGY

Part I--Business Risk Analysis

Industry risk

9. Within the framework of Standard & Poor's corporate criteria for assessing industry risk (See "Methodology: Industry Risk," Nov. 19, 2013), we view pharmaceuticals as a "low risk" industry (category 2). We derive this industry risk assessment from our view of the industry's "low risk" (category 2) cyclicality, and our assessment that the industry warrants a "low risk" (category 2) assessment for competitive risk and growth.

Cyclicality

10. We assess cyclicality for pharmaceutical companies as "low risk" (category 2). Historical data supports this view, showing very low cyclicality of revenues and low cyclicality of profitability, which are the two key measures used to derive an industry's cyclicality assessment. Based on our analysis of global Compustat data, pharmaceutical companies experienced an average peak-to-trough (PTT) decline in revenues of only 0.2% during recessionary periods since 1952, and a PTT decline of 0.4% during the severe 2007-2009 recession. The EBITDA margin of pharmaceutical companies experienced an average PTT decline of 4.0% , and a modest decline of 1.8% in the 2007-2009 recession.

11. Demand for pharmaceuticals is somewhat shielded from general macroeconomic cycles because disease occurrence and prevalence (in developed countries) do not vary with the economy. Some products are truly essential. Government-paid or provided pharmaceuticals provide a large safety net, though eligibility and prices paid are often pared when government budgets are strained. In the U.S., demand can be slightly sensitive to the employment rate, in part, because lack of a job may mean lack of drug insurance for people of working age and their children (although the Affordable Care Act could lessen this phenomenon). Patients may defer routine check-ups (where drugs are prescribed), ration drugs, or seek lower-cost therapies for economic reasons.

12. Volatility in a pharmaceutical company's revenues and profitability is more likely to reflect its own new product launches and the market entrance of competing products, rather than broad macroeconomic conditions. This is a key factor in our credit analysis.

Competitive risk and growth

13. We view the pharmaceutical industry as warranting a "low risk" (category 2) competitive risk and growth assessment. To evaluate competitive risk and growth, we assess four subfactors as low, medium, or high risk. These subfactors are:

- Effectiveness of industry barriers to entry;
- Level and trend of industry profit margins;
- Risk of secular change and substitution by products, services, and technologies; and
- Risk in growth trends.

14. When we evaluate some of the above subfactors, we make distinctions among branded drugs, generic drugs, and CMOs.

Effectiveness of pharmaceutical industry's barriers to entry--Low Risk

15. ***Branded:*** Patents provide formidable but temporary barriers to entry. Patents are typically for 20 years, but a company may spend the first five years or so developing the drug before it is put on the market. Thus, effective market exclusivity (due to patent protection) is roughly 15 years. Most markets in which rated pharmaceutical companies compete have strong patent protection laws, although challenges have become more aggressive. When patent protection ends, generic drugs can capture 95% of prescription volume in the first year. Third-party (government and private) payors, political leaders, distributors, and retailers encourage the substitution of generics for branded drugs. Most consumers (patients) choose cheaper generics.

16. Market exclusivity can also be gained through technology, such as drug and device combinations, which are difficult to copy, or regulatory barriers (for biologics), which are often more effective and may last longer.

17. A new branded drug must be approved by regulators in each country. Its efficacy and safety must be demonstrated in extensive clinical trials. The costly and time-consuming approval process, combined with patent protection, forms a major barrier to entry.

18. Substantial costs, time, and research and development (R&D) expertise are required to discover, develop, and commercialize new drugs. Heavy investments must be made years before revenues are generated, and there is a high failure rate for new drugs. The costs and specialized skills needed for late-stage development encourage market entrants to seek established partners, rather than try to compete with them.

19. Even when patents or other barriers to entry are substantial and there is limited, if any, competition, drug price controls exist in nearly all countries except the U.S.

20. ***Generic:*** Although entry barriers for manufacturers of traditional generic drugs are lower than those for branded drug producers (in part, because clinical trials are not required for traditional generics), they are still high and effective in limiting competitive entrants. We believe a successful generic drug company needs broad scale, scope, and diversity, which deters upstart entrants. For makers of generic biologic drugs (a.k.a. biosimilars), for which clinical trials are required, the costs, risks, and entry barriers are similar to those for makers of branded drugs.

21. ***CMO:*** Governments mandate high quality standards for drug manufacturing, which limits competition for CMOs. Stringent manufacturing standards and necessary certifications provide barriers to entry for CMOs when contracts are awarded, and deter customers from switching contractors when production is underway. Large pharmaceutical customers have created additional entry barriers because they increasingly prefer fewer CMO vendors and they seek vendors that can provide a wide range of services in multiple geographic markets.

Level and trend of pharmaceutical industry profit margins--Low Risk

22. ***Branded:*** The branded pharmaceutical industry overall has had very high and stable profit margins, supported by patent protection and pricing flexibility, despite the substantial shift to generic drugs (which account for about 84% of U.S. prescriptions, according to the IMS Institute for Healthcare Informatics, May 9, 2013). Even after a drug has faced

generic competition for years, it may still enjoy price flexibility on the remaining volume used by patients (and prescribed by physicians) who continue to prefer the higher-priced branded drug. A longer period of healthy profits can be achieved if the drug is approved for OTC sale. Price flexibility is greatest in the U.S., where government-mandated price restrictions are limited. The existence of price controls in other markets with strong patent protection diminishes the industry's still-strong global profit potential, and also affects our view of geographic diversity (see Competitive Position section).

23. Each blockbuster product (with more than $1 billion of annual sales) typically experiences a life cycle of high margins when it enjoys market exclusivity, and much lower margins when generic competitors enter the market. This cyclical pattern for one or a few key products can drive a company's overall profit margins.

24. Generally robust gross profit margins of branded pharmaceutical companies also reflect relatively low manufacturing costs. However, R&D costs are substantial, typically 15% to 20% of revenues. Marketing and other selling, general, and administrative (SG&A) costs vary according to a product's life cycle. Pharmaceutical companies are increasingly outsourcing some product development and manufacturing, which tends to reduce their costs and makes expenses more flexible. We believe outsourcing has helped to preserve strong margins in recent years.

25. ***Generic:*** Generic drug producers typically have significantly lower margins than producers of branded drugs because generics, to a large degree, compete on price. Generic prices and margins follow a pattern that echoes the experience for branded drugs. Prices and margins fall as more competitors enter the market. In accordance with U.S. regulations (Hatch Waxman Act of 1984), the first approved generic drug generally competes only with the branded drug for the first six months after the patent on the branded drug expires; then, other FDA-approved generics are permitted to enter the market (the rule does not apply to some therapeutic categories). This pattern can result in some profit margin volatility for generic drug makers, although the effects can be muted when a company has a large and diverse portfolio of generic drugs at different stages in the life cycle.

26. Profit margins for generic drug companies are enhanced by relatively low R&D and marketing costs, compared with those of branded drug producers.

27. ***CMO:*** CMOs generally lack pricing power, which contributes to their relatively low profit margins. Pharmaceutical company customers often have two CMO sources and have considerable power in negotiating contracts with CMOs. The CMO business is also fairly capital-intensive, which can hurt profit margins when revenues dip.

28. Pharmaceutical companies are more commonly affected by risks associated with patent litigation and product liability than companies in most other industries. Profits may be hurt by the loss of patent protection, costs of patent litigation, and penalties for patent infringement. Product liability claims give rise to litigation costs and potentially to settlement payments and damage to a company's reputation with customers, which can result in lost sales and market share.

Risk of secular change and substitution of pharmaceuticals by products, services, and technologies--Low Risk

29. Over a multiyear period, new branded pharmaceuticals often replace older drugs. However, there is minimal risk of product substitution from other industries. In limited circumstances, a patient and his physician may choose between a pharmaceutical or other therapy, such as surgery. In a few therapeutic areas (e.g., treatment of allergy symptoms), prescription pharmaceuticals may compete with OTC drugs.

30. We expect the CMO industry to benefit from a continuing gradual trend among pharmaceutical companies, and more rapidly growing bio-pharmaceutical companies, to outsource manufacturing. Still, a specific CMO is exposed to the

risk that a customer might cancel or not renew a contract and award it to another CMO. We believe it is highly unlikely a customer would decide to in-source manufacturing of a specific product that was previously outsourced, but the customer might decide to curtail outsourcing of other products.

Risk in pharmaceutical industry growth trends--Medium Risk

31. The pharmaceutical industry is well established and we expect its global revenues to grow between 1% and the nominal rate of GDP growth over the medium-term, given that nominal GDP growth is greater than 1%. Patent expirations (which usually lead to the substitution of a cheaper generic for a more expensive branded drug, effectively lowering total revenue for the medicine) and price regulation in many countries dampen revenue growth. However, we expect global industry volume (including lower-priced generics) to continue growing at a mid-single-digit annual rate. We expect further generic penetration of the total prescription drug market, now about 84% in the U.S. based on volume (number of prescriptions) and about 50% of volume (dispensed medicines) in Europe (according to the European Generic Medicines Association), which enhances growth prospects for generic drug makers.

32. Growth is spurred by innovation, new diagnostic techniques, and new treatments for diseases or conditions that were previously undetected or treated less effectively. For example, drugs that are tailored to a patient's genetic composition account for a small portion of the market now, but we expect them to expand rapidly.

33. Pharmaceutical growth also benefits from favorable demographic and economic trends. In developed economies, long-term demand is fueled by lifestyle changes (e.g., more sedentary) and the growing number of older people, who consume a disproportionate share of drugs. An expanding middle class aids growth in developing economies, which account for an increasingly significant portion of global pharmaceutical sales. Positive global trends largely offset utilization controls imposed by government and other third-party payors in developed markets, which can hinder growth of newer and typically more expensive drugs.

34. We expect a continuing gradual trend to outsource manufacturing, leading to a somewhat higher growth rate for contract manufacturers than for the total pharmaceutical industry.

Country risk

35. Country risk plays a critical role in determining all ratings on companies in a given country. Country-related risk factors can substantially affect company creditworthiness, both directly and indirectly. A key factor in our business risk analysis for corporate issuers is the country risk assessment, which includes the broad range of economic, institutional, financial market, and legal risks that arise from doing business in a specific country. In assessing country risk for a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria). We primarily measure a company's exposure to country risk based on the percent of its revenues generated in each significant country or region, unless the percent of EBITDA is available, in which case we use the percent of EBITDA.

Competitive position (including profitability)

36. Under our corporate criteria, a company's competitive position is assessed as (1) "excellent," (2) "strong," (3) "satisfactory," (4) "fair," (5) "weak," or (6) "vulnerable." In assessing the competitive position of pharmaceutical companies we review an individual company's

- Competitive advantage;
- Scale, scope, and diversity;
- Operating efficiency; and
- Profitability.

37. The first three components are independently assessed as either (1) "strong," (2) "strong/adequate," (3) "adequate," (4) "adequate/weak," or (5) "weak." We assess the fourth component through the combination of the level and the volatility of profitability.

38. After assessing separately competitive advantage; scale, scope, and diversity; and operating efficiency, we determine the preliminary competitive position assessment by ascribing a specific weight to each component. The applicable weightings will depend on the company's Competitive Position Group Profile (CPGP).

39. The CPGP assigned to developers and marketers of branded pharmaceuticals is "Services and Product Focus," reflecting the premium pricing and opportunity for product differentiation (derived from innovation) enjoyed by participants.

40. The CPGP assigned to developers and manufacturers of generic drugs is "Commodity Focus/Scale Driven" because competition is mainly based on price with limited product or service differentiation. Operating efficiency is more important for producers of generics than for producers of branded drugs, and this factor is given more weight in in the Commodity Focus/Scale Driven CPGP. When a company makes both branded and generic drugs and each contributes at least 20% of revenue, we assess each business separately using a different CPGP.

41. The CPGP assigned to CMOs is "Capital or Asset Focus," reflecting the capital intensity of this subsector and the relative importance of operating efficiency, including the ability to meet stringent regulatory requirements.

42. If medical devices or OTC medicines account for 20% or more of a pharmaceutical company's revenues or EBITDA, we separately assess the competitive position of those businesses, in accordance with our global corporate criteria (as explained in "Key Credit Factors For The Health Care Equipment Industry," Nov. 19, 2013, and "Key Credit Factors For The Branded Nondurables Industry," Nov. 19, 2013, respectively).

43. We derive a company's preliminary competitive position assessment from three components, and weigh them according to the CPGP as shown below.

Table 1

Competitive Position Components

	Services and Product Focus	Commodity Focus/Scale Driven	Capital or Asset Focus
Competitive advantage	45%	10%	30%
Scale, scope, and diversity	30%	55%	30%
Operating efficiency	25%	35%	40%
Total	100%	100%	100%

44. Although we place different weights on the components depending on the CPGP, we use substantially the same elements to assess each component, regardless of the CPGP.

Competitive advantage

45. ***Branded:*** When we analyze the competitive advantage of a branded pharmaceutical company, we focus on the company's ability to achieve consistent revenue growth with steady (or improving) profit margins, despite the life cycles of individual products; in particular, the sharp decline in a specific product's earnings associated with the entrance of generic competition. Our assessment is forward-looking. We estimate the revenue a company may lose over the next few years as a result of its products losing market exclusivity, and we compare this to our estimate of potential revenue from products in an advanced stage of development and early commercialization. R&D capabilities are extremely important in the pharmaceutical industry. Marketing capabilities generally play a lesser role, but may distinguish the stronger companies.

46. Our overall competitive advantage assessment blends both quantitative and qualitative factors including:

- Pipeline quality (itself a function of the number of new molecular entities (NMEs), and the percent of lost sales replaced);
- Market exclusivity profile (as defined below);
- Number of blockbuster drugs;
- R&D strategy;
- Marketing and brand recognition; and
- Leverage with distributors.

47. We assess the quality of a company's new product pipeline, including its ability to replace lost sales, as shown in table 2. First, we determine the number of NMEs. Then, we measure the replacement of lost sales as follows: total estimated maximum potential sales over the next three years from a) products approved by regulators in the past two years, b) products filed for regulatory approval, and c) products in late-stage (phase III) clinical development, as a percent of revenue estimated to be lost due to loss of market exclusivity resulting from patent expiration. We calculate a weighted average of the NMEs and pipeline replacement assessments, which forms the pipeline quality assessment.

Table 2

Pipeline Quality

		Weight
Number of New Molecular Entities*		**30%**
Strong	>15	
Strong/adequate	10 to 15	
Adequate	7 to 10	
Adequate/weak	4 to 7	
Weak	<4	
Pipeline's Replacement of Lost Sales (%)		**70%**
Strong	>90	
Strong/adequate	70-90	
Adequate	50-70	
Adequate/weak	30-50	
Weak	<30	

*In late-stage (phase III) development.

48. We also count the number of blockbuster drugs a branded drug company currently has on the market, as indicated

below. Blockbusters enhance a company's competitive position because they have especially high profit margins that can finance R&D, which in turn could generate future earnings and cash flow.

49. Number of approved blockbuster drugs ($1 billion or more annual sales):

- Strong: 7 or more
- Adequate: 4-6
- Weak: 3 or fewer

50. We define "market exclusivity profile" as the percent of branded pharmaceutical sales expected to face generic competition in the next three years. We may relax the guidelines shown below if there are non-patent barriers to entry, such as those for orphan drugs.

51. Market exclusivity profile:

- Strong: Less than 10%
- Adequate: 20% to 30%
- Weak: More than 30%

52. A branded pharmaceutical company with a "strong" or "strong/adequate" competitive advantage assessment has all or most of the following characteristics:

- Its pipeline quality assessment is "strong" or "strong/adequate";
- It has a market exclusivity profile below 10%;
- It has seven or more blockbuster drugs and consistently develops them, indicating its R&D prowess;
- Its R&D strategy is consistent with its capabilities and market conditions;
- It has the marketing skill and muscle to reach professionals who prescribe, and consumers; its products achieved favorable brand recognition; and
- It can command favorable terms from distributors, hospitals, and retailers because its high volume gives it clout with them.

53. A branded pharmaceutical company with a "weak" or "adequate/weak" assessment of its competitive advantage has most of the following characteristics:

- Its pipeline quality assessment is "weak" or "adequate/weak";
- Its market exclusivity profile is more than 30%;
- It has three or fewer blockbuster drugs;
- It lacks clout with distributors, hospitals, and retailers, generally indicated by ranking below the top 100 in global drug sales; and
- It has a history of substantial or repeated regulatory sanctions for marketing practices or manufacturing problems.

54. ***Generic:*** For generic drug companies, our competitive advantage analysis focuses on speed-to-market, manufacturing expertise, and volume-derived clout with customers.

55. A generic drug company with a "strong" or "strong/adequate" assessment of competitive advantage typically has the following characteristics:

- It is consistently the first to file an abbreviated new drug application in the U.S. (ANDA; which confers six months of

sales free of other generic competitors);
- It has a significant amount of special manufacturing expertise (e.g., topical applications, liquid dosing, and transdermal patches);
- It can command favorable terms from distributors, hospitals, and retailers because its high volume gives it clout with them.

56. A generic drug company with a "weak" or "adequate/weak" assessment of competitive advantage has most of the following characteristics:

- It has minimal ability to attain first-to-file status;
- It has limited, if any, ability to manufacture special formulations;
- It lacks clout with distributors, hospitals, and retailers, generally indicated by ranking below the top 100 in global drug sales; and
- It has a history of substantial or repeated regulatory sanctions for marketing practices or manufacturing problems.

57. ***CMO:*** CMOs generally have limited competitive advantages because the market is extremely fragmented, highly competitive, and price-sensitive. These market dynamics give much more bargaining power to pharmaceutical companies that outsource manufacturing relative to the contract manufacturers.

58. A CMO with a "strong/adequate" (or rarely "strong") competitive advantage assessment would likely have:

- Special manufacturing expertise (e.g., for liquids or transdermal patches); and
- A proven history of working with regulators without any serious adverse findings.

59. A CMO with a "weak" or "adequate/weak" competitive advantage assessment has at least one of the following characteristics:

- It does not have special manufacturing expertise; and/or
- It has a history of regulatory issues or adverse FDA findings, especially if they resulted in temporary or permanent plant closings.

Scale, scope, and diversity

60. When we evaluate scale, scope, and diversity of pharmaceutical companies, the nature and emphasis of our analysis is different for the three pharmaceutical subsectors.

61. ***Branded:*** For a branded pharmaceutical company we assess four subfactors of scale, scope, and diversity:

- Product diversity;
- Therapeutic diversity;
- Geographic diversity and presence in the U.S.; and
- Market leadership (a function of the size of the most significant therapeutic market it serves and its share of that market).

62. Rather than narrowly assessing the scale of R&D (the activity for which scale is most relevant), we recognize the results of a company's R&D efforts in our competitive advantage assessment. Nor do we separately assess the scope of a branded drug company's activities because scope is encompassed in our therapeutic diversity assessment.

63. ***Product diversity:*** Product diversity is important because a specific product may face new competition (especially when its patent expires) and a product could be withdrawn from the market after the recognition of a serious side-effect or a manufacturing misstep. We view animal health as an additional product and therapeutic category within pharmaceuticals. We assess product diversity--expressed as product concentration in the table below--based on percent of sales. We average the assessments for the top product and top three products.

Table 3

Product Concentration

Assessment	Top product	Top 3 products
Strong	< 25%	< 50%
Adequate	25% - 40%	50% - 70%
Weak	>40%	>70%

64. ***Therapeutic diversity:*** Therapeutic diversity is important, in part, because a company's drugs in one therapeutic area (e.g., oncology) can become obsolete when a competitor introduces a breakthrough product. In addition to simply measuring the revenue contribution from the company's largest therapeutic category, we put this in the context of the size of the category and the company's leadership position (or lack thereof) in it.

65. We derive our therapeutic diversity assessment, based on the percent of sales contributed by the company's largest therapeutic categories (TCs), as shown below. We average the assessments for the top TC and three largest TCs.

Table 4

Therapeutic Diversity Assessment

	Contribution of largest TC	Contribution of 3 largest TCs
Strong	<35%	<60%
Adequate	35% - 55%	60% - 80%
Weak	>55%	>80%

66. ***Geographic diversity and presence in the U.S.:*** Geographic diversity can reduce profit declines that may result from unfavorable economic, reimbursement, regulatory, or other developments in a specific country or region. However, the size of the U.S. market and its absence of price controls make it especially attractive. Therefore a high concentration of sales in the U.S. is usually viewed favorably.

67. A branded pharmaceutical company with "strong" geographic diversity and U.S. presence has some of the following characteristics:

- Nearly all of its sales are in countries with strong patent protection;
- The U.S. market accounts for more than 80% of its sales; and
- Its percent of sales from emerging markets is at least equal to the pharmaceutical industry average.

68. A branded pharmaceutical company with "adequate" geographic diversity and U.S. presence has one of the following characteristics:

- Its geographic mix of sales is similar to the geographic mix for the global pharmaceutical industry (about half in the U.S.; 15% in Europe, the Middle East, and Africa; and the remainder in the rest of the world);
- The U.S. market accounts for 50%-80% of its sales; or
- Western Europe accounts for 75% or more of its sales.

69. A branded pharmaceutical company with weak geographic diversity and U.S. presence has some of the following characteristics:

- More than 20% of its sales are in countries with weak patent protection;
- It derives more than 50% of its sales from one country other than the U.S.; and
- It derives less than 10% of its revenue from emerging markets.

70. ***Market leadership:*** Our market leadership assessment evaluates the company's market share within a particular therapeutic category. This is an important distinction because therapeutic markets are different in size (for example, cardiovascular is much larger than gastrointestinal), and some companies may have a strong market share in a small therapeutic category while others may have weak market share in a large therapeutic category. That is why, when assessing therapeutic market leadership, we first evaluate the relative size of the therapeutic category.

71. For a company's top therapeutic category we determine our market leadership assessment in a three-step process, as follows:

- Assess the relative size of the therapeutic market;
- Determine the company's market share in that therapeutic category; and
- Combine the relative size and market share assessments to determine the company's market leadership assessment.

72. For a company's largest therapeutic category, we measure the size of that category as a percent of the total pharmaceutical industry. The percent ranges correspond to assessments, as shown in table 5.

Table 5

Therapeutic Market Relative Size		
Strong	>10%	1
Strong/Adequate	7-10%	2
Adequate	4-7%	3
Adequate/Weak	2-4%	4
Weak	<1%	5

73. We assess a company's market share in its top therapeutic category in accordance with table 6.

Table 6

Market Share Assessment		
Strong	>20%	1
Strong/Adequate	15-20%	2
Adequate	10-15%	3
Adequate/Weak	5-10%	4
Weak	<5%	5

74. The market leadership assessment is an average of the relative size and market share assessments giving equal weight to the two components, rounded to the nearest category. We calculate the average using the numbers in the last columns of tables 5 and 6. For example, a company with an "adequate" (category 3) market size assessment and a "strong" (category 1) market share assessment would have a "strong/adequate" (category 2) market leadership assessment.

75. For branded drug companies our overall scale, scope, and diversity assessment is a blend of the four diversity components. We look first at the "center of gravity." For example, two diversity assessments of "weak," a market leadership assessment of "adequate/weak," and one diversity assessment of "strong/adequate" would suggest an overall assessment of "adequate/weak." We may adjust the scale, scope, and diversity assessment by one category (e.g., from "adequate" to "strong/adequate") if one factor is especially strong or weak, or to reflect potential changes, such as our expectation that the company's product diversity will improve.

76. ***Generic:*** For a generic pharmaceutical company we assess the following four subfactors of scale, scope, and diversity:

- Overall market penetration, indicated by its global sales ranking among generic drug companies;
- Market share trends;
- Geographic diversity of revenue base and manufacturing footprint; and
- Technical capabilities.

77. Large generic drug companies can achieve more therapeutic diversity than their branded counterparts. For example, the leading generic drug companies address nearly all major therapeutic categories, compared with perhaps 5-10 for the leading branded drug companies. We do not explicitly measure therapeutic diversity for generic drug companies because we believe this is captured in their sales rankings. For producers of generic drugs, which typically have numerous and frequently changing product portfolios, product diversity is less relevant than it is for branded drug companies. We also evaluate geographic diversity and scope of technical capabilities of generic drug companies. We believe a company's ability to produce specialized or more complex products, such as injectable medicines, topical drugs, transdermal patches, extended release drugs, and biosimilars is a positive attribute, which diversifies its business. A generic company with "strong" or "strong/adequate" scale, scope, and diversity has some of the following characteristics:

- It ranks among the top 5 global generic drug companies based on revenue;
- Its global market share is growing;
- It has a strong presence in all major geographic drug markets, including the U.S. and western Europe;
- Its manufacturing base is reliable and geographically diversified; and
- It has the ability to produce specialized generic drugs; it has a variety of formulation capabilities to handle more complex products.

78. A generic company with "weak" or "adequate/weak" scale, scope, and diversity has some of the following characteristics:

- It ranks below the top 10 global generic drug companies based on revenue;
- It is losing market share;
- Its revenues are largely concentrated in only one country other than the U.S.;
- Its manufacturing is concentrated (e.g., only one facility) with little or no back-up mechanism; and
- It has a minimal ability to produce specialized or more complex generic formulations.

79. ***CMO:*** For CMOs we qualitatively incorporate therapeutic and geographic diversity in our view of scale, scope, and diversity. In addition, these companies are especially exposed to risks of customer and product concentration. A customer could cancel production of a product and select a different CMO for the next-generation product, or choose to manufacture it in-house. There is also a low-probability risk that the customer would shift production of a current product or sever its relationship with a specific CMO, perhaps in the wake of quality problems or as a result of the

customer's financial distress. We evaluate this exposure as follows:

80. A contract manufacturer with "strong" or "strong/adequate" customer diversity has all of the following characteristics:

- Its top customer accounts for less than 10% of its revenue;
- Its top 10 customers account for less than 50% of its revenue;
- Its client base is skewed to large pharmaceutical and biotech companies; and
- Its relationships with key clients are broader than manufacturing (e.g., it participates in product development).

81. A contract manufacturer with "weak" or "adequate/weak" customer diversity has some of the following characteristics:

- One customer accounts for 30% or more of its revenue;
- Its top five customers account for 80% or more of its revenue; and
- It has a high exposure to small pharmaceutical and biotech companies.

Operating efficiency

82. Operating efficiency is usually a secondary consideration for branded drug companies because production costs are relatively low as a percent of revenue. We believe efficient manufacturing is generally less important than in most other industries, but it is especially relevant for CMOs. We consider the critically important effectiveness of R&D investments, a major expense for branded drug companies, in our assessments of competitive advantage, scale, scope, and diversity of both branded and generic drug companies. Our operating efficiency assessment of them also takes account of a drug company's ability to quickly bring a promising drug to market.

83. When we assess a pharmaceutical company's operating efficiency, we look at:

- The company's ability to maintain profit margins during stressful periods (e.g., losing market exclusivity for a key drug);
- The nature and flexibility of its cost structure;
- Working capital management; and
- The absence or presence of manufacturing problems.

84. The outsourcing of research, manufacturing, or sales is not necessarily viewed positively or negatively.

85. A pharmaceutical company with "strong" or "strong/adequate" operating efficiency has the following characteristics:

- It maintains stable margins even during adverse conditions;
- It has a track record of success in bringing new products through development in a timely manner;
- It is skilled in navigating the patent and regulatory approval processes;
- Its raw material costs are relatively modest (higher for CMOs); and
- It has good working capital management.

86. A pharmaceutical company with "weak" or "adequate/weak" operating efficiency has some of the following characteristics:

- It experiences a pronounced decline in profitability during adverse conditions;
- It has a history of material or repeated regulatory sanctions for marketing practices or manufacturing problems; it is unable to quickly remedy problems;
- It has excess staffing (R&D, sales and marketing, etc.) or manufacturing capacity;

- It has onerous or volatile raw material costs; and
- It has poor working capital management.

Profitability

87. The profitability assessment can confirm or modify the preliminary competitive position assessment. The profitability assessment consists of the level and the volatility of profitability. The two components are combined into the final profitability assessment using a matrix (see our global corporate criteria).

Level of profitability

88. We determine the level of profitability on a three-point scale: "above average," "average," and "below average."

89. We use the EBITDA margin (adjusted for nonrecurring items) to assess the level of profitability because it is indifferent to the mix of debt and equity in the capital structure and is not distorted by acquisitions and share repurchases that are common in the industry. Consistent with the global corporate criteria, we generally use two years of historical data, and our forecast for the current year and the following two years. We use the guidelines shown in Tables 7 or 8 to classify the level of profitability for a pharmaceutical company.

Table 7

Branded Level of Profitability

	EBITDA Margin
Above average	Greater than 40%
Average	30% to 40%
Below average	Less than 30%

Table 8

Generic and CMO Level of Profitability

	EBITDA Margin
Above average	Greater than 30%
Average	20% to 30%
Below average	Less than 20%

90. We use one set of guidelines for branded drug companies and a different set for generic drug companies and CMOs. The guidelines are lower for generic drug companies because they have less risk of profit volatility associated with the loss of market exclusivity, compared with branded drug companies. There are not a sufficient number of rated CMOs from which we can derive meaningful benchmarks just for this subsector.

Volatility of profitability

91. The volatility of profitability is assessed on a six-point scale, from: "1" (least volatile) to "6" (most volatile).

92. In accordance with our global corporate criteria, we generally assess the volatility of profitability using the standard error of regression (SER), subject to having at least seven years of historical annual data. We use EBITDA margin to determine the SER for pharmaceutical companies because this measure tends to be less affected by merger and acquisition activity than absolute EBITDA or return on capital.

Part II--Financial Risk Analysis

Accounting and analytical adjustments

93. In assessing the accounting characteristics of pharmaceutical companies, the analysis uses the same methodology as with other corporate issuers. Our analysis of a company's financial statements begins with a review of its accounting to determine whether the statements accurately measure a company's performance and position relative to its peers and the larger universe of corporate entities. To allow for globally consistent and comparable financial analyses, our rating analysis may include quantitative adjustments to a company's reported results. These adjustments also enable better alignment of a company's reported figures with our view of underlying economic conditions. Moreover, they allow a more accurate portrayal of a company's ongoing business. Adjustments that pertain broadly to all corporate sectors, including this sector, are discussed in "Corporate Methodology: Ratios And Adjustments," published Nov. 19, 2013.

94. The most significant adjustment we employ for pharmaceutical companies is to net "surplus cash" against debt, in accordance with our ratios and adjustments criteria.

Cash flow/leverage analysis

95. In assessing the cash flow adequacy of a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria). Cash flow/leverage analysis is assessed on a six-point scale ranging from (1) "minimal" to (6) "highly leveraged." These assessments are determined by aggregating the assessments of a range of credit ratios, predominantly cash flow-based, which complement each other by focusing attention on the different levels of a company's cash flow waterfall in relation to its obligations.

Core ratios

96. For each company, we determine (in accordance with our ratios and adjustments criteria) two core credit ratios: FFO to debt and debt to EBITDA. We usually use debt to EBITDA as the primary leverage measure for pharmaceutical companies.

Supplemental ratios

97. In addition to our analysis of a company's core ratios, we also consider supplemental ratios in order to develop a fuller understanding of a company's credit risk profile and fine tune our cash flow analysis. If the preliminary cash flow and leverage assessment indicated by the core ratios is "significant" or weaker, we place more emphasis on EBITDA interest coverage as a supplemental ratio. We may also consider FFO plus interest to cash interest coverage when a company has payment-in-kind (PIK) debt, PIK preferred stock, or low-coupon convertible debt. These ratios recognize the low or lack of cash expense on an ongoing basis.

98. We use the supplemental debt payback ratios (cash flow from operations to debt, free operating cash flow to debt, and discretionary cash flow to debt) infrequently. These measures usually do not provide additional insight, in part, because pharmaceutical companies generally have moderate fixed and working capital requirements relative to all other industries.

Benchmark volatility table

99. For pharmaceutical companies with a Corporate Industry and Country Risk Assessment (CICRA) of '2' or worse, we use the "standard volatility" table for cash flow and leverage benchmarks.

Part III--Rating Modifiers

Diversification/portfolio effect

100. In assessing the diversification/portfolio effect on a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria).

Capital structure

101. In assessing a pharmaceutical company's capital structure, we use the same methodology as with other corporate issuers (see global corporate criteria).

Financial policy

102. In assessing financial policy of a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria).

Liquidity

103. In assessing the liquidity of a pharmaceutical company, our analysis uses the same general methodology as with other corporate issuers (see global corporate criteria and "Methodology And Assumptions: Liquidity Descriptors For Global Corporate Issuers," published Jan. 2, 2014).

Management and governance

104. In assessing management and governance of a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria).

Comparable ratings analysis

105. In assessing the comparable ratings analysis of a pharmaceutical company, our analysis uses the same methodology as with other corporate issuers (see global corporate criteria).

RELATED CRITERIA AND RESEARCH

- Methodology And Assumptions: Liquidity Descriptors For Global Corporate Issuers, Jan. 2, 2014
- Corporate Methodology, Nov. 19, 2013
- Methodology: Industry Risk, Nov. 19, 2013
- Corporate Methodology: Ratios And Adjustments, Nov. 19, 2013
- Country Risk Assessment Methodology And Assumptions, Nov. 19, 2013
- Methodology: Management And Governance Credit Factors For Corporate Entities And Insurers, Nov. 13, 2012
- Principles Of Credit Ratings, Feb. 16, 2011

106. These criteria represent the specific application of fundamental principles that define credit risk and ratings opinions. Their use is determined by issuer- or issue-specific attributes as well as Standard & Poor's Ratings Services' assessment of the credit and, if applicable, structural risks for a given issuer or issue rating. Methodology and assumptions may change from time to time as a result of market and economic conditions, issuer- or issue-specific factors, or new empirical evidence that would affect our credit judgment.