

3SBio, Inc. SSRX (NAS)

| Last Close | Industry | Sector |
|------------|---------------|------------|
| 11.60 USD | Biotechnology | Healthcare |

Profile

Pricing data through 10 Feb 2012

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3SBio Inc. is a fully integrated, profitable biotechnology company focused on researching, developing, manufacturing and marketing biopharmaceutical products mainly in China. 3SBio's recombinant, or genetically engineered, protein-based products and product candidates are designed to address markets with unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious diseases. The company's main products are EPIAO and TPIAO and its legacy products are Intefen and Inleusin. Launched in 1998, EPIAO is an injectable recombinant human erythropoietin, or EPO, that is used to stimulate the production of red blood cells in patients with anemia and to reduce the need for blood transfusions. In 2007, the company received from the SFDA licenses to produce and sell pre-filled syringe EPIAO in 2,000 IU, 3,000 IU, 4,000 IU and 10,000 IU strengths. 3SBio launched TPIAO, its newest internally developed protein-based therapeutic product, in January 2006. This product is a TPO indicated for the treatment of chemotherapy-induced thrombocytopenia, a deficiency of platelets. In addition to EPIAO and TPIAO, it markets two other protein-based therapeutic that had historically been contributors to its overall revenues. Intefen is the company's recombinant interferon alpha-2a product. Intefen is indicated for the treatment of carcinomas of the lymphatic or hematopoietic system, such as lymphoma and leukemia and viral infectious diseases, such as hepatitis C. It launched Intefen in the Chinese market in 1995. The Company's product pipeline, which it expects will be a key contributor to its future growth, consists of six product candidates in various stages of development. 3SBio's main products target markets with unmet medical needs in nephrology, oncology, supportive cancer care, inflammation and infectious disease. The company is currently focused on expanding the indication for its marketed products, developing next generation, enhanced versions of its marketed products and bringing novel protein-based therapeutics to market. 3SBio mainly sources its raw materials from a number of international suppliers through their local distributors. The company's Shenyang-based manufacturing operations consist of bulk manufacturing and formulation, fill and finish activities for the production of

EPIAO, TPIAO, Intefen, Inleusin and other product candidates for both clinical and commercial purposes. 3SBio also manufactures its product candidates for clinical trials at this facility. All filling, finishing and packaging activities in relation to its domestic sales are conducted at its Shenyang facility. The company currently markets its products through distribution agreements with local agents in several developing countries, consisting of Egypt, Pakistan, Thailand, Brazil, Mexico, Trinidad and Tobago, Guatemala and Columbia. 3SBio selects its distributors based on their reputation, market coverage and sales experience. It conducts credit assessments of each of its distributors or hospital customers before it enters into a purchase agreement. In addition to EPIAO and TPIAO, the company markets two protein-based therapeutics that have historically been contributors to its overall revenue. In particular, 3SBio faces competition from domestic and foreign pharmaceutical companies in each of its potential product areas.

3SBio, Inc. SSRX

Sales USD Mil 77 **Mkt Cap USD Mil** 254 **Industry** Biotechnology **Sector** Healthcare

3SBio is a Chinese biotechnology company involved in the development, manufacture, and sales of genetically-engineered pharmaceuticals. The company produces proteins which can be used as treatment for diseases such as rheumatoid arthritis, cancer, and autoimmune deficiencies. 3SBio sells its products throughout China under the Shenyang Sunshine brand.

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| Growth Rates | Compound Annual | | | | |
|----------------------|-----------------|------|------|-------|--|
| | 1 Yr | 3 Yr | 5 Yr | 10 Yr | |
| Revenue % | 32.1 | 32.4 | 32.1 | — | |
| Operating Income % | 2.9 | 21.3 | 33.4 | — | |
| Earnings/Share % | -3.6 | -1.8 | 27.1 | — | |
| Dividends % | — | — | — | — | |
| Book Value/Share % | 8.9 | 5.6 | — | — | |
| Stock Total Return % | -23.3 | 30.9 | -6.2 | — | |
| +/- Industry | -48.0 | 20.0 | -9.5 | — | |
| +/- Market | -24.9 | 13.4 | -4.8 | — | |

| Profitability Analysis | Current | 5 Yr Avg | Ind | Mkt |
|------------------------|--------------------|----------|------|--------|
| | Return on Equity % | 8.0 | 17.9 | 8.5 |
| Return on Assets % | 7.6 | 11.0 | 4.5 | 9.5 |
| Fixed Asset Turns | 2.6 | 3.1 | 3.6 | 7.5 |
| Inventory Turns | 2.5 | 2.2 | 1.5 | 16.1 |
| Revenue/Employee USD K | 107.6 | 80.9* | — | 1049.9 |
| Gross Margin % | 89.2 | 90.9 | 83.7 | 38.3 |
| Operating Margin % | 19.5 | 24.5 | 24.3 | 16.7 |
| Net Margin % | 18.5 | 26.2 | 10.3 | 11.2 |
| Free Cash Flow/Rev % | — | — | 14.8 | 0.1 |
| R&D/Rev % | 9.2 | 0.1 | — | 9.7 |

| Financial Position | 09-10 USD Mil | | 09-11 USD Mil | |
|---------------------|---------------|----|---------------|----|
| | Cash | 23 | — | 24 |
| Inventories | 3 | — | 4 | — |
| Receivables | 20 | — | 25 | — |
| Current Assets | 120 | — | 146 | — |
| Fixed Assets | 30 | — | 31 | — |
| Intangibles | 7 | — | 8 | — |
| Total Assets | 180 | — | 201 | — |
| Payables | 1 | — | 2 | — |
| Short-Term Debt | — | — | — | — |
| Current Liabilities | 7 | — | 10 | — |
| Long-Term Debt | — | — | — | — |
| Total Liabilities | 8 | — | 12 | — |
| Total Equity | 172 | — | 189 | — |

| Valuation Analysis | Current | 5 Yr Avg | Ind | Mkt |
|----------------------|----------------|----------|------|------|
| | Price/Earnings | 17.6 | 24.7 | 55.0 |
| Forward P/E | 12.2 | — | — | 13.5 |
| Price/Cash Flow | 28.2 | 27.5 | 30.2 | 7.4 |
| Price/Free Cash Flow | — | — | 39.7 | 16.9 |
| Dividend Yield % | — | — | 0.2 | 2.0 |
| Price/Book | 1.3 | 1.8 | 4.7 | 2.0 |
| Price/Sales | 3.3 | 6.4 | 5.8 | 1.2 |
| PEG Ratio | 0.0 | — | — | 1.4 |

Morningstar Rating **Last Price** 11.60 **Fair Value** **Uncertainty** **Economic Moat™** **Stewardship Grade**



| 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | YTD | Stock Performance |
|------|------|------|------|------|-------|------|------|-------|------|------|--------------------|
| — | — | — | — | — | -47.6 | 75.5 | 10.9 | -32.7 | 13.5 | 13.5 | Total Return % |
| — | — | — | — | — | -9.1 | 52.1 | -1.9 | -32.7 | 6.7 | 6.7 | +/- Market |
| — | — | — | — | — | -40.4 | 69.0 | 7.0 | -42.5 | 1.0 | 1.0 | +/- Industry |
| — | — | — | — | — | — | — | — | — | 0.0 | 0.0 | Dividend Yield % |
| — | — | — | — | — | 323 | 168 | 295 | 337 | 224 | 254 | Market Cap USD Mil |

| 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | TTM | Financials |
|------|------|------|------|------|------|------|------|------|------|------|--------------------------|
| — | — | 9 | 9 | 13 | 16 | 24 | 35 | 46 | 62 | 77 | Revenue USD Mil |
| — | — | — | 80.6 | 84.8 | 91.0 | 90.3 | 91.1 | 92.0 | 90.1 | 89.2 | Gross Margin % |
| — | — | — | 1 | 3 | 5 | 6 | 7 | 12 | 13 | 15 | Oper Income USD Mil |
| — | — | — | 7.9 | 19.7 | 28.6 | 26.9 | 19.6 | 26.6 | 20.7 | 19.5 | Operating Margin % |
| — | — | 0 | 1 | 2 | 4 | 11 | 6 | 12 | 12 | 14 | Net Income USD Mil |
| — | — | 0.00 | 0.01 | 0.14 | 0.26 | 0.51 | 0.26 | 0.56 | 0.55 | 0.64 | Earnings Per Share USD |
| — | — | — | — | — | — | — | — | — | — | — | Dividends USD |
| — | — | — | 100 | 100 | 15 | 15 | 21 | 22 | 22 | 22 | Shares Mil |
| — | — | — | — | — | 5.95 | 6.27 | 6.89 | 7.78 | 8.75 | 8.74 | Book Value Per Share USD |
| — | — | — | 1 | 3 | 5 | 9 | 9 | 13 | 9 | 9 | Oper Cash Flow USD Mil |
| — | — | — | 0 | -1 | 0 | -2 | -6 | -14 | -12 | -13 | Cap Spending USD Mil |
| — | — | — | 1 | 2 | 4 | 8 | 3 | -1 | -4 | -4 | Free Cash Flow USD Mil |

| 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | TTM | Profitability |
|------|------|------|------|------|------|------|------|------|------|------|--------------------|
| — | — | — | 4.5 | 10.9 | 20.6 | 14.6 | 4.1 | 8.3 | 7.3 | 7.6 | Return on Assets % |
| — | — | — | 27.0 | 49.6 | 53.1 | 16.0 | 4.2 | 8.6 | 7.6 | 8.0 | Return on Equity % |
| — | — | 0.7 | 8.6 | 15.7 | 23.8 | 45.3 | 16.2 | 26.3 | 19.4 | 18.5 | Net Margin % |
| — | — | — | 0.53 | 0.69 | 0.86 | 0.32 | 0.25 | 0.32 | 0.37 | 0.41 | Asset Turnover |
| — | — | — | 6.0 | 3.7 | 1.9 | 1.0 | 1.0 | 1.0 | 1.0 | 1.1 | Financial Leverage |

| 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 09-11 | Financial Health |
|------|------|------|------|------|------|------|------|------|------|-------|-------------------------|
| — | — | — | 1 | -1 | 6 | 119 | 117 | 119 | 113 | 136 | Working Capital USD Mil |
| — | — | — | 4 | — | 3 | — | — | — | — | — | Long-Term Debt USD Mil |
| — | — | — | 3 | 5 | 9 | 129 | 135 | 148 | 172 | 189 | Total Equity USD Mil |
| — | — | — | 1.22 | — | 0.34 | — | — | — | — | — | Debt/Equity |

| 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | TTM | Valuation |
|------|------|------|------|------|------|------|------|------|------|------|-----------------|
| — | — | — | — | 27.7 | 29.2 | 24.3 | 26.9 | 15.5 | 17.6 | 17.6 | Price/Earnings |
| — | — | — | — | — | — | — | — | 0.9 | 1.2 | 1.2 | P/E vs. Market |
| — | — | — | — | 12.6 | 4.7 | 6.4 | 5.3 | 2.9 | 3.3 | 3.3 | Price/Sales |
| — | — | — | — | 2.5 | 1.2 | 2.0 | 2.0 | 1.2 | 1.3 | 1.3 | Price/Book |
| — | — | — | — | 32.9 | 19.1 | 22.7 | 37.9 | 24.8 | 28.2 | 28.2 | Price/Cash Flow |

| Quarterly Results | | | | | | |
|------------------------|--------|--------|--------|--------|--|--|
| Revenue USD Mil | Sep 10 | Dec 10 | Mar 11 | Sep 11 | | |
| Most Recent Period | 15.1 | 17.9 | — | 22.9 | | |
| Prior Year Period | 10.9 | 14.1 | 15.5 | 17.1 | | |
| Rev Growth % | Sep 10 | Dec 10 | Mar 11 | Sep 11 | | |
| Most Recent Period | 39.1 | 27.0 | — | 34.4 | | |
| Prior Year Period | -81.9 | -79.4 | -81.0 | -81.6 | | |
| Earnings Per Share USD | Sep 10 | Dec 10 | Mar 11 | Sep 11 | | |
| Most Recent Period | 0.04 | 0.15 | — | 0.23 | | |
| Prior Year Period | 0.09 | 0.17 | 0.17 | 0.14 | | |

| Industry Peers by Market Cap | | | | |
|------------------------------|-----------------|-------------|------|------|
| | Mkt Cap USD Mil | Rev USD Mil | P/E | ROE% |
| 3SBio, Inc. | 254 | 77 | 17.6 | 8.0 |
| Amgen Inc | 59044 | 15450 | 16.7 | 15.8 |
| Biocon Ltd. | — | — | — | — |

| Major Fund Holders | | % of shares |
|--------------------|--|-------------|
| | | — |
| | | — |
| | | — |

*3Yr Avg data is displayed in place of 5Yr Avg

TTM data based on rolling quarterly data if available; otherwise most recent annual data shown.

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Management & Ownership

Management Activity

| Name | Position | Shares Held | Report Date* | InsiderActivity |
|------|----------|-------------|--------------|-----------------|
| NA | NA | NA | NA | NA |

*Report date represents the date on which the owner's common shares held was audited.

Fund Ownership

| Top Owners | Morningstar Rating | % of Shares Held | % of Fund Assets | Change (k) | Portfolio Date |
|---|--------------------|------------------|------------------|------------|----------------|
| Pictet-Generics-HR EUR | QQQQ | 3.45 | 2.23 | -72 | 31 Jul 2011 |
| Fidelity China Special Situations PLC | | 3.21 | 1.01 | 736 | 31 Aug 2011 |
| Fidelity VIP Mid Cap Inv | QQQQ | 2.15 | 0.07 | 0 | 31 Dec 2011 |
| BlackRock Health Sciences Opps Inv A | QQQQ | 2.13 | 0.29 | 0 | 31 Dec 2011 |
| Pictet-Global Megatrend Selection -HR € | QQQ | 0.99 | 0.30 | -19 | 31 Jul 2011 |

Concentrated Holders

| | | | | | |
|--|------|------|------|-----|-------------|
| PPF CP Global BioPharma | | 0.18 | 3.55 | 41 | 31 Dec 2010 |
| PHARMA/wHEALTH W/WELLINGTON | | 0.17 | 3.10 | 3 | 31 Jan 2012 |
| Delta Lloyd L Health Development I Acc | Q | 0.43 | 2.98 | 19 | 31 Oct 2011 |
| Pictet-Generics-HR EUR | QQQQ | 3.45 | 2.23 | -72 | 31 Jul 2011 |

Institutional Transactions

| Top 5 Buyers | Morningstar Rating | % of Shares Held | % of Fund Assets | Shares Bought/Sold (k) | Portfolio Date |
|--|--------------------|------------------|------------------|------------------------|----------------|
| Fidelity China Special Situations PLC | | 3.21 | 1.01 | 736 | 31 Aug 2011 |
| OMGB Fidelity Pacific | | 0.70 | 0.27 | 124 | 31 Dec 2011 |
| Edinburgh Worldwide | QQQ | 1.04 | 1.04 | 57 | 30 Sep 2011 |
| PPF CP Global BioPharma | | 0.18 | 3.55 | 41 | 31 Dec 2010 |
| Delta Lloyd L Health Development I Acc | Q | 0.43 | 2.98 | 19 | 31 Oct 2011 |

Top 5 Sellers

| | | | | | |
|---------------------------------|------|------|------|------|-------------|
| Fidelity Overseas | QQ | 1.09 | 0.13 | -201 | 31 Dec 2011 |
| Federated Kaufmann Small Cap A | QQ | 0.35 | 0.09 | -160 | 31 Dec 2011 |
| AST Federated Aggressive Growth | QQQ | 0.20 | 0.09 | -77 | 31 Dec 2011 |
| Pictet-Generics-HR EUR | QQQQ | 3.45 | 2.23 | -72 | 31 Jul 2011 |

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Industry Focus: Biotechnology

Don't Bail on Biotech

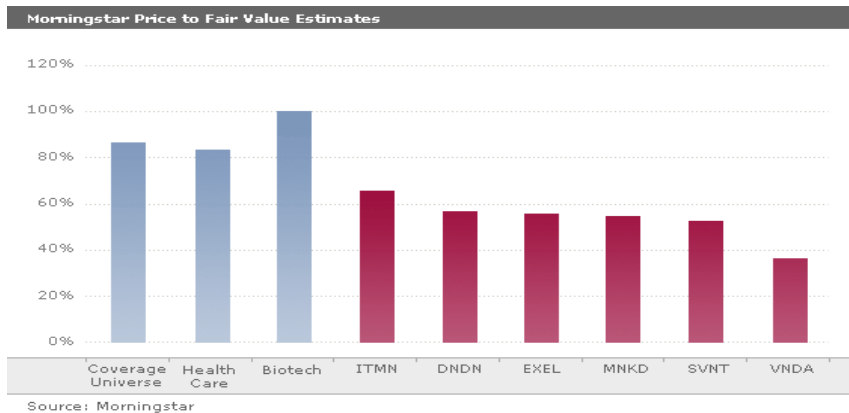
02 November 2011

Lauren Migliore
Stock Analyst

We see opportunity as fleeing investors trigger an irrational sell-off.

The biotechnology sector has been hit especially hard as investors flee high-risk assets amid recent market uncertainty. Compounding this heightened risk aversion is increased concern regarding product concentration for one-drug operations and the ability of development-stage biotechs to access equity markets in the wake of plummeting stock values. Furthermore, Dendreon's DNDN announcement that sales of prostate cancer drug Provenge will come in well under the market's initial expectations for the year caused a ripple effect throughout the sector as investors dumped shares of firms nearing the launch of other highly anticipated drugs. Investors also appear to be unloading shares of unprofitable biotechs with dwindling cash balances on the concern that volatile market conditions will limit firms' ability to raise capital. We think the market's indiscriminate sell-off of risky assets presents attractive risk/reward trade-offs for investors who can handle the ride. Specifically, market overreaction has pushed shares of Dendreon, InterMune ITMN, Exelixis EXEL, Savient Pharmaceuticals SVNT, Vanda Pharmaceuticals VNDA, and MannKind MNKD to

attractive levels, in our opinion. With the exception of MannKind (which enjoys the financial backing of billionaire entrepreneur Alfred Mann), all of these biotechs have at least a year's worth of cash on hand, which should provide them with more flexibility to wait and tap the equity markets under more favorable conditions. Dendreon: We think the market's overreaction to the firm's commercialization troubles presents a buying opportunity. In its second-quarter results, the company withdrew its sales guidance for Provenge (often referred to as the "world's first cancer vaccine"), causing shares to plummet 65% overnight. The drug is one of the most expensive cancer treatments on the market, and concern over its high price tag prompted the Centers for Medicare Medicaid Services to conduct a national coverage analysis for the drug during the last year. Although Dendreon received a favorable ruling in June, it seems the company has done a bad job educating physicians about Provenge's coverage status, and persistent reimbursement uncertainty has resulted in stagnant sales. Although we have significantly lowered our sales forecast for the company's sole marketed product, we think Provenge remains an important treatment option for prostate cancer patients. Provenge has demonstrated the ability to meaningfully improve survival without the toxic effects of chemotherapy. The novel immunotherapy has been shown to extend median survival by 4.1 months in clinical trials, putting it on par with some of the most efficacious cancer drugs, like Roche's RHHBY Avastin. The steep sell-off in Dendreon's shares is unmerited, in our opinion. InterMune: Dendreon's announcement that Provenge sales would come in well under the market's initial expectations caused a ripple effect throughout the biotech sector as investors dumped shares of firms nearing the launch of other highly anticipated drugs. With its stock price falling 25% since Dendreon's announcement, rare-disease-focused biotech InterMune has been no exception. Despite securing the blessing of a Food and Drug Administration advisory panel, InterMune received a complete response letter for lead drug Esbriet, which is for the treatment of idiopathic pulmonary fibrosis. However, the firm received marketing authorization for Esbriet in Europe at the end of February,



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and we expect the drug to contribute meaningfully to revenue next year. With the potential for orphan-drug exclusivity and a critical unmet need among patients, we think Esbriet can claim a hefty price tag and garner InterMune blockbuster sales once it eventually reaches the worldwide market. InterMune plans to conduct another Phase III trial to support domestic approval. We think the drug eventually will clinch FDA approval considering the lack of treatment options for the disease, its prior regulatory approval in Japan, and its demonstrated efficacy in one of two Phase III trials. Esbriet could hit the U.S. market by 2014, potentially propelling the firm to profitability that same year. We believe Esbriet has the potential to generate \$2 billion in peak sales once it makes it to market worldwide.

Exelixis: Exelixis' shares have been under pressure since Bristol-Myers Squibb (BMY) decided last year to pass on co-development rights to Exelixis' lead drug candidate cabozantinib. Bristol instead chose to focus on its own late-stage oncology pipeline rather than broaden the scope of cabozantinib's development plan. Exelixis shares have fallen more than 40% since this summer as investors shed high-risk assets and register their concern about the firm's lack of funding support for cabozantinib, especially following the firm's inability to secure a Special Protocol Assessment from the FDA. Yet promising data released after Bristol's decision reinforced our optimistic assessment of cabozantinib's potential, and we think retaining exclusive rights could turn out to be a net positive for the firm if it is able to partner cabozantinib under more attractive terms further down the development timeline. In a midstage randomized discontinuation trial, Exelixis reported that cabozantinib demonstrated broad activity across multiple tumor types. Most significantly, cabozantinib demonstrated a very high disease control rate and reduction in bone lesions in patients with metastatic castrate-resistant prostate cancer. Bone metastases are the primary cause of prostate cancer morbidity and mortality, and cabozantinib appears to have a differentiated mechanism of action through simultaneous effects on both soft tissue and bone metastases. This benefit is distinct from any other agent: Chemotherapy has a modest impact on survival but no

impact on bone disease, while bone-targeted therapy fights lesions but does not deter cancer progression. We expect Exelixis will conduct multiple regulatory filings for its lead drug. If successful, we think cabozantinib could bring in more than \$1 billion in sales for prostate cancer alone.

Savient Pharmaceuticals: Higher-than-expected costs, uncertainty around the firm's European plans, and a 500-point decline in the Dow sent shares of Savient tumbling following its report of second-quarter earnings. We have lowered our fair value estimate, but we still think the sell-off has created a buying opportunity. Our revised fair value has pushed back the firm's break-even point to 2014 due to higher selling, general, and administrative costs, lowered our United States peak sales for the firm's gout treatment Krystexxa to \$500 million from \$600 million, and lowered the chance of a European partnership to 25%. With no commercialization experience and Savient's attention focused elsewhere on selling its business, Krystexxa's launch was destined for a slow start. However, we do not think the slow launch necessarily signals a lack of demand for the treatment. Savient has faced a number of mostly temporary setbacks that have delayed Krystexxa's launch, but we expect them to dissipate during the next year. Savient is now fully staffed with its salesforce, managers, and marketing team for Krystexxa, and we think the firm's attentions are now solely focused on the drug.

Vanda Pharmaceuticals: A surprise approval following a nonapprovable letter from the FDA and a new commercialization deal with Novartis (NVS) propelled Vanda's stock price from \$1 per share to nearly \$15 per share in May 2009. However, since then, the stock has fallen dramatically as investors have registered their disappointment with Fanapt's slow start and the product concentration risk of Vanda overall. Although sales growth continues to track below our expectations, we believe Fanapt has not been given enough time to gain traction in the market. The drug demonstrated good efficacy and a favorable side-effect profile in trials, and we think it eventually will make it into the prescribing rotation of doctors accustomed to cycling schizophrenia patients through multiple drugs. In the near term, we expect

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prescription growth in the U.S. to be supplemented by Fanapt's expansion abroad. In addition, we think Fanapt's growth trajectory could be further enhanced by approval of a long-acting formulation of the drug. A long-acting injectable formulation has the potential to boost efficacy and compliance for patients and could represent an important new treatment option. Vanda also announced that it has expanded its clinical development program for remaining pipeline candidate tasimelteon. If trials prove successful, we think tasimelteon potentially could add to revenue as soon as 2013. The firm's existing valuation near cash levels implies minimal sales of Fanapt, limiting the potential downside for investors. We think the upside remains significant should Fanapt gain traction or Vanda's remaining pipeline drug sees approval. MannKind: MannKind is positioning lead product Afrezza as a differentiated diabetes therapy that offers superior safety and efficacy to injectable insulin. Despite these advantages, MannKind has received two complete response letters from the FDA. We think the agency's request for more inhaler data will delay approval by two years, hastening the firm's cash burn and probably causing investors to suffer more dilution before the company can reach profitability. Given the FDA's additional trial requirements, we think MannKind to will have to wait until 2013 to see product revenue, and its dwindling cash balance probably will force it to raise additional capital within the next year. As a result, investors have sold off shares of MannKind on the concern that volatile market conditions will limit the firm's ability to raise capital to support Afrezza's potential commercialization. However, we already have incorporated a fairly dilutive equity raise within the next year into our valuation of the company, and we think current trading levels represent an overreaction to MannKind's liquidity constraints, especially when considering that the firm enjoys the financial backing of billionaire entrepreneur Alfred Mann (who has invested a large portion of his net worth in the company and has financed the lion's share of Afrezza's development costs to date). We continue to think the chances of Afrezza eventually receiving the green light are high, given the limited nature of the FDA's concerns. That said, MannKind

remains a speculative investment. With a rising debt load and only early-stage drugs remaining in its pipeline, shareholders are likely to be left empty-handed if MannKind is unable to meet agency demands for Afrezza.