Celgene Corporation CELG

by Karen Andersen

Analyst Note 04-30-2009

Celgene's CELG first-quarter revenue grew roughly 30% compared with the first quarter of 2008 despite the effects of a weak economy, thanks to Revlimid's growing market share and ongoing global launch, as well as U.S. sales of Vidaza. We're maintaining our fair value estimate.

Despite the severity of the illnesses that Celgene's drugs aim to treat, the economy is clearly impacting the firm's results. In March, management warned that earnings per share and revenue should only reach the bottom end of previously released projections for 2009. More than half of the firm's U.S. revenue stems from Medicare, and the high price tag associated with Revlimid and Thalomid means that patients hit the donut hole of Part D coverage only about a month into treatment. The impact of this is particularly noticeable in the first quarter, as new patients enroll in Part D. More patients with prescriptions are failing to fill them, and increased co-pay assistance and free drug are boosting Celgene's operating expenses. Distributors are also drawing down their inventories due to the economy, affecting stocking levels and Celgene's reported sales.

Outside of economic effects, underlying demand for Celgene's products looks strong. The leading drug in multiple myeloma, Revlimid generated $363 million in sales in the first quarter, as a higher percentage of patients are taking Revlimid, and for longer periods of time. Revlimid recently received a recommendation from the National Institute for Health and Clinical Excellence (NICE) in the U.K., an endorsement for the benefit of Revlimid treatment outweighing its costs. If Celgene hopes to meet its revenue projections for the year, a successful U.K. launch will be a critical piece of this performance. We think Vidaza sales should continue to impress in 2009, as the percentage of new MDS patients taking Vidaza has virtually doubled in the past year, and the European launch is just beginning. We're eager to see Phase II data (expected midyear) for Celgene's apremilast in psoriatic arthritis; this oral drug could compete with other immunological agents such as Amgen's AMGN Enbrel in the long run.

Thesis 02-23-2009

Celgene is in the midst of a global expansion led by its blood cancer drug Revlimid, and the recent $2.8 billion acquisition of Pharmion only adds to the strength of its portfolio. We think Celgene still faces several competitive and regulatory risks, and that Pharmion's portfolio offers only short-term growth at a steep price. However, Revlimid's success and the potential of Celgene's growing cancer and immunoinflammatory drug pipeline give Celgene a narrow economic moat.

Celgene funded its rich pipeline with sales of Thalomid, a drug that led to thousands of birth defects when it entered the market in the 1950s. Celgene recognized the drug's

Morningstar Rating
★★★

Stock Price
As of 04-30-2009
$42.72

Fair Value Estimate
$54.00

Consider Buying
$27.00

Consider Selling
$108.00

Fair Value Uncertainty
High

Economic Moat
Narrow

Stewardship Grade
C

Bulls Say

- Revlimid continues to generate impressive data in approved and potential new indications, and Celgene has numerous trials in the works to expand usage to several additional forms of cancer.
- Celgene's acquisition of Pharmion--which brought global rights to Thalomid and Vidaza--further solidifies this firm's strategic focus on blood-related cancer therapies.
- Celgene's strong growth and profitability could make it an attractive takeout target for large pharmaceutical or biotech firms looking to expand their oncology-focused product portfolios.
- Celgene has a strong pipeline beyond Revlimid, including drugs that could treat diseases such as psoriasis and various forms of cancer.
- Although Thalomid is generally associated with more side effects than the newer Revlimid, its long history of use in multiple myeloma provides a hedge against any possible Revlimid safety problems down the road.

Bears Say

value to treat the blood cancer known as multiple myeloma, and with a system in place to restrict distribution, Thalomid has achieved annual U.S. sales of more than $400 million. Although patents on the molecule have expired, Celgene's patented STEPS distribution system and various other formulation patents have kept generic competition at bay.

Celgene is looking to a less toxic and more potent derivative of Thalomid, known as Revlimid, for future growth. Revlimid received Food and Drug Administration approval for low-risk myelodysplastic syndrome (MDS) at the end of 2005 and relapsed multiple myeloma in mid-2006. Revlimid sales increased to $1.3 billion in 2008, a sizable portion of Celgene's $2.3 billion top line. Although Thalomid will remain an important part of multiple myeloma therapy--particularly in Europe, where its lower price tag could boost top-line growth--it should take a backseat to Revlimid in the long term, and we think Revlimid sales will reach $2.8 billion by 2011.

However, Celgene's challenges shouldn't be underestimated. Revlimid has quickly penetrated the U.S. low-risk MDS market, and while Pharmion's Vidaza (approved to treat high-risk patients) should significantly add to growth from MDS sales, the drug could be vulnerable to generic competition in 2011. Reimbursement challenges in the U.S. and abroad remain a threat, and competitive pressures are also mounting. Teva TEVA-owned Barr Pharmaceuticals is attempting to launch a generic version of Thalomid and while Celgene is preparing its application for Revlimid use in newly diagnosed patients, competing multiple myeloma drug Velcade received U.S. Food and Drug Administration approval for its own label expansion in mid-2008.

Revlimid's international sales and additional clinical studies will probably require a significant amount of time to mature, but the firm continues to make progress, and its diverse pipeline gives us reason to believe in this biotech's longevity and competitive advantages.

Valuation

We're raising our fair value estimate for Celgene to $54 per share from $49 to factor in the likelihood that a larger drug firm acquires Celgene. We think Celgene's oncology drug portfolio and prospects for rapidly improving profitability make it an attractive target, and we think the firm could be acquired at roughly a 25% premium to recent trading prices. We still believe Revlimid will achieve $2.8 billion in sales by 2011, and we see Celgene's total revenue that year reaching $4 billion. We think U.S. sales of Vidaza should peak at almost $400 million before losing orphan drug exclusivity in 2011, but we assume orphan drug exclusivity will protect European sales significantly beyond this date. Although we've accounted for Thalomid's recent approval in Europe, we expect long-term sales to be limited by Revlimid's uptake. Given Revlimid's 95% gross margin and Gilead Sciences' GILD success with its small-molecule drugs, we continue to see 50% operating margins in Celgene's future. We assume an 11% cost of equity for Celgene.

Risk

Although Celgene maintains a patented compliance and patient education program, there is a risk that any newfound toxicity could hurt the sales potential of Revlimid and other thalidomide derivatives in development. Celgene could also struggle to establish itself internationally because it doesn't plan to partner Revlimid with a larger, more established global pharmaceutical player. Generic firms could find a way to bypass Thalomid's formulation patents, and the lower cost of a generic Thalomid would mute sales of both Thalomid and Revlimid. Celgene may also struggle to obtain reimbursement for Revlimid internationally, given the drug's high price tag.

- Revlimid's safety profile is still being elucidated, and the drug requires a restricted distribution program similar to Thalomid's STEPS program. Although this is not problematic for currently approved indications, significant safety studies will be required if these drugs are eventually used to treat broader indications such as rheumatoid arthritis.
- Velcade, long thought to play second fiddle to Celgene's Revlimid in multiple myeloma treatment, has produced outstanding trial results and is vying with Revlimid in the first-line setting.
- Revlimid sales will cannibalize sales of Thalomid, stunting initial sales growth in the multiple myeloma market.
- Lauched at $54,000 a year to treat MDS and $74,000 per year to treat multiple myeloma, the cost of Revlimid fuels legislator and health insurer debates regarding cancer drug pricing. With no plans to follow in the footsteps of Amgen AMGN and Genentech by capping cost to patients, this could lead to pricing pressure down the road.
- Teva-owned Barr Pharmaceuticals has filed for approval of a generic version of Thalomid. If it is able to bypass Celgene's method-of-use patents, it could dramatically reduce Celgene's Thalomid sales when it reaches the market in a couple of years.

Close Competitors	TTM Sales $Mil	Market Cap $Mil

Celgene Corporation	**2,397**	**21,219**
* Amgen, Inc.	14,698	58,525

* Morningstar Analyst Report Available

Data as of 03-31-09

Strategy

Celgene is capitalizing on its thalidomide expertise to develop and commercialize less-toxic derivatives such as Revlimid to treat cancer and other diseases. Celgene has worldwide rights to Revlimid and the rest of its pipeline, which boosts potential returns to shareholders. Celgene's recent acquisition of Pharmion gave it rights to cancer drug Vidaza, and strategic acquisitions in stem cell technology and signal proteins have given Celgene one of the strongest diversified research pipelines we've seen.

Management & Stewardship

John Jackson retired as chairman and CEO in 2006, after nearly a decade of service. Longtime president and COO Sol Barer replaced Jackson as CEO and chairman; despite his substantial experience and Celgene's success, we think his $10 million in total compensation for 2007 seems excessive. We're also disappointed by the composition of the board; seven of Celgene's nine directors are considered independent, but four of them have been on the board for more than 10 years, which casts doubt on their true level of independence. On the basis of these factors, we think Celgene warrants a Stewardship Grade of C. On a more positive note, annual option issuance is now below 3% of shares outstanding, and we're happy with Barer's level of ownership. We were also pleased to see that well-qualified newcomers arrived in time for Revlimid's launch. Mark Alles, vice president of marketing, joined in 2004 with 11 years of experience at Aventis Oncology SNY. Shawn Tomasello, vice president of sales, joined Celgene in 2005 with 16 years of experience at Genentech DNA. Alles' involvement in the marketing of cancer blockbuster Taxotere and Tomasello's experience leading the salesforce for another cancer blockbuster, Rituxan, make them uniquely qualified for their roles at Celgene.

Profile

Celgene is a biopharmaceutical firm that discovers, develops, and markets therapeutics for the treatment of cancer and immunological diseases. Celgene markets Thalomid to treat multiple myeloma and Revlimid, a less toxic thalidomide derivative, to treat MDS and multiple myeloma. The acquisition of Pharmion gave Celgene global rights to Thalomid, as well as MDS drug Vidaza. Celgene also has discovery capabilities in cell-signaling pathways and stem cell research.

Growth

As Revlimid's explosive growth levels begin to moderate and Thalomid's growth turns negative, we expect to see 25% top-line growth in 2009. We expect 10-year average sales growth of 12%.

Profitability

Due to Revlimid's strong sales, Celgene's profitability continues to expand rapidly. Charges related to the acquisition of Pharmion pushed Celgene into the red in 2008, but given the sky-high gross margin on Revlimid, we think operating margins north of 50% are achievable in the long term.

Financial Health

With about $2.2 billion in cash on its balance sheet at the end of 2008, Celgene should have the resources it will require to market Revlimid, integrate Pharmion, and continue its international expansion.

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