Gilead and Bristol Report Encouraging Hepatitis C Data, Supporting Our Sales Forecasts

by Damien Conover, CFA
Director
Analysts covering this company do not own its stock.


Currency amounts expressed with “$” are in U.S. dollars (USD) unless otherwise denoted.

Gilead and Bristol-Myers Squibb released data for several key hepatitis C studies in conjunction with the annual meeting of the European Association for the Study of the Liver in Barcelona, and we’re maintaining our fair value estimates on each firm. Bristol reported early Phase II data demonstrating that its NS5A inhibitor daclatasvir could lead to a 100% cure rate when used in combination with Gilead’s 7977 in certain patient populations, and Gilead’s own study updates showed promising data from the ELECTRON and QUANTUM studies, as well as an early study of an in-house all-oral regimen (without 7977) that gives us a glimpse of the potential of an earlier NS5A inhibitor, GS-5885. We’re encouraged by the positive data from both firms, as we think this serves as confirmation of our thesis that Gilead’s prior disappointing Genotype I data in null responders (a difficult-to-treat population of patients who have failed previous therapy) was not indicative of 7977’s overall potential in the broader Genotype I population.

We also continue to see room for Abbott’s hepatitis C portfolio to take an important role in future therapy, given positive data earlier this month for a combination of protease inhibitor ABT-333, polymerase inhibitor ABT-450, and ribavirin in the CO-PILOT study. Because these data fall short of the 100% cure rates seen in Bristol’s trial, we plan to slightly lower our projections for ABT-450 and ABT-333. However, we don’t expect a material change in our fair value estimate for Abbott. We note that uncertainty remains around the efficacy and side effect profiles for all of these drug candidates, as the data presented so far only pertain to small Phase II studies. Based on the number of promising candidates in trials, we expect the global hepatitis C market to grow rapidly over the next several years, reaching $22 billion by 2020.

Thesis Feb. 16, 2012 | Damien Conover, CFA
On the foundation of a wide lineup of patent-protected drugs, a leading diagnostics business, a strong nutritional division, and a top-tier vascular group, Abbott Laboratories has dug a wide economic moat. We expect these operating lines will continue to generate strong returns and drive growth. Further, the company’s decision to split itself into two is likely to result in two well-positioned companies (a drug company and a diversified health-care company) with strong competitive advantages.

Existing drugs and new pipeline products should propel long-term growth. Abbott’s pharmaceutical division contains a diverse set of growing blockbuster across many therapy groups. Autoimmune agent Humira, HIV/AIDS drug Kaletra, and cardiovascular treatments Tricor and Trilipix lead the group with more than $8 billion in annual sales (27% of total sales). Humira continues to be the workhorse of the group with 21% growth in 2011, as new indications help propel the drug. The company’s active research and development efforts are creating the next potential blockbusters with several hepatitis C drugs and kidney disease drug bardoxolone showing particularly strong clinical data.

Outside the pharmaceutical group, Abbott runs top-tier diagnostic and nutritional segments that generate more than 25% of total sales, helping to insulate the company from patent losses in the drug group. The diagnostic group is well positioned as disease therapy becomes more patient-specific.

Complementing the pharmaceutical, diagnostic, and nutritional segments, the firm’s recently expanded vascular line is poised for rapid growth. Favorable clinical data on the company’s new drug-coated stent Xience versus entrenched Boston Scientific stent Taxus has resulted in fast market uptake.

In addition to strong internal operating lines, Abbott has a successful record of acquisitions and partnerships. The favorable acquisitions of Knoll and Kos Pharmaceuticals brought in Humira and Niaspan along with pipeline
products. The acquisition of Guidant’s vascular business opened the door to a new operating segment and Xience, a drug-eluting stent superior to an in-house stent. Additionally, the recent acquisitions of Advanced Medical Optics and the drug units from Solvay and Piramal should add value over the long term. The strong record and ample cash flow raise our confidence that external growth opportunities will probably augment internal growth.

Valuation, Growth and Profitability

We are slightly increasing our fair value estimate to $70 from $68 per share based on our increased projections for the company’s hepatitis C drugs. Base on recent clinical data, we have increased our sales projection for ABT-333, ABT-267, and ABT-450, which led to the increased fair value. Our new fair value estimate implies a 2012 price/earnings multiple of 14 times. The current forward-year industry price/earnings multiple is 10 times, and we believe Abbott’s industry-leading growth continues to warrant a premium multiple valuation for the company. We incorporated the recent acquisition of Piramal’s drug unit into our valuation model, but acquired sales largely offset the high purchase price. Humira represents the most important driver in Abbott’s valuation—we project it contributes more than 20% to our estimate of the firm’s total value. While competing drugs lurk in the near future, we expect Humira to post double-digit annual growth during the next several years. Overall, during the next five years, we project 6% average annual sales growth, led by Humira, Xience, and acquisitions. During the same period, we project slightly increasing operating margins, as cost-containment initiatives offset patent losses on high-margin drugs. We estimate a 9% cost of equity and a similar weighted average cost of capital, which reflect the secure and robust cash flows derived from diverse operations.

Risk

While Abbott maintains diverse operations, it depends heavily on Humira and Xience for future growth. Further, the company’s pipeline isn’t as large as those of rivals, making any failures with late-stage candidates very costly. Also, the company faces typical industry risks including drug delays or nonapprovals, as well as an increasingly aggressive generic and managed-care industry.

Bulls Say

- Strong clinical data on safety and efficacy give Abbott’s stent Xience a leg up in the drug-eluting stent market.
- Aggressive cost-cutting plans should propel Abbott’s bottom-line growth much quicker than top-line growth.
- International markets and indications in Crohn’s disease and psoriasis for Humira should further propel sales growth for the company’s leading pharmaceutical product.
- The recent acquisition of Piramal’s drug unit increases Abbott’s exposure to the rapidly growing Indian market.
- The decision to split the company into two could increase the transparency of each unit, which could help investors see the value in the different operations.

Bears Say

- Splitting the company into two could create distractions...
for management as well as reverse cost synergies such as increasing duplicative areas of operations.

- Lack of robust internal development casts a shadow on the company’s ability to create blockbusters in-house.
- Clinical data on drug-eluting stents have recently presented unclear benefits versus bare-metal stents and other treatments. Stent operations and use of drug-eluting stents could fall without supportive new data.
- To prepare for more tuck-in acquisitions, Abbott is probably going to add cash to its balance sheet rather than pursue aggressive share buybacks. The investment community could react negatively toward decisions in favor of acquisitions over returning cash to shareholders via share repurchases.
- Pfizer’s JAK-3 inhibitor for rheumatoid arthritis has shown strong efficacy in Phase III trials relative to Humira. If the drug holds up well in late-stage trials, it could take significant market share from Humira based on the drug’s oral dosing. Also, Roche’s RA drug Actemra is poised to reported head-to-head data versus Humira in late 2011 or early 2012. Strong Actemra data could translate into Humira market share losses.

Financial Overview
Financial Health: Thanks to its acquisitions, Abbott holds less cash than its peers. However, Abbott’s robust and relatively stable cash flows should easily meet interest expenses with ample reserves left for share repurchases, increases to dividends, and small acquisitions.

Company Overview
Profile: Abbott manufactures and markets pharmaceuticals, medical devices, blood glucose monitoring kits, and nutritional health-care products. Products include prescription drugs, coronary and carotid stents, and nutritional liquids for infants and adults.

Following the Advanced Medical Optics acquisition, Abbott also markets eye-care products. Abbott generates slightly less than 60% of revenue from pharmaceuticals.

Management: Miles White took the helm as CEO in 1998 and chairman of the board the following year. His tenure with the company dating back to 1984 provides the experience needed in handling the many operating lines of the company. Under his leadership, the company executed several value-enhancing acquisitions. After the split, White will continue as the CEO of the diversified company, and longtime Abbott executive Richard Gonzalez will take the CEO spot at the pharmaceutical-focused firms. We believe both executives have strong records that bode well for future leadership.

Overall, the company promotes solid stewardship. We like the policy of cumulative voting rights in the election of directors, as this gives more clout to minority shareholders. Compensation for top executives is well balanced between cash and equity and in line with industry practices. However, we would like the company to take a page from the major European pharmaceutical companies and split the roles of CEO and chairman.
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**Analyst Notes**

### Apr. 19, 2012
**Gilead and Bristol Report Encouraging Hepatitis C Data, Supporting Our Sales Forecasts**

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We also continue to see room for Abbott’s hepatitis C portfolio to take an important role in future therapy, given positive data earlier this month for a combination of protease inhibitor ABT-333, polymerase inhibitor ABT-450, and ribavirin in the CO-PILOT study. Because these data fall short of the 100% cure rates seen in Bristol’s trial, we plan to slightly lower our projections for ABT-450 and ABT-333. However, we don’t expect a material change in our fair value estimate for Abbott. We note that uncertainty remains around the efficacy and side effect profiles for all of these drug candidates, as the data presented so far only pertain to small Phase II studies. Based on the number of promising candidates in trials, we expect the global hepatitis C market to grow rapidly over the next several years, reaching $22 billion by 2020.

### Apr. 18, 2012
**Abbott Posts Strong 1Q, Driven by Robust Humira and Nutritional Sales**

Abbott Laboratories reported strong first-quarter results that slightly beat our expectations and consensus. However, we don’t expect any changes to our fair value estimate of $70 based on the minor outperformance. We continue to believe Abbott is undervalued as the company’s key drug Humira for immunology disease along with several business lines including the nutritional business appears underevaluated by the investment community. Also, Abbott is making strong strides in developing its pipeline.

In the quarter, total sales increased 6% operationally versus the prior-year period, led by strong Humira growth (up 19% year over year) as well as robust nutritional sales growth (up 10% year over year). Earnings per share increased 13% year over year, outpacing sales growth as gross margins increased more than 250 basis points thanks to cost savings and positive product mix. Based on the strong first-quarter results, Abbott increased its full-year earnings per share forecast by $0.05 to $5.00-$5.10, which we expect it will easily meet.

We continue to project robust Humira growth over the next several years, given only limited penetration in key immunology indications. Over the next three years, we estimate Humira will post double-digit growth, which should help offset Abbott’s slowing growth in more mature products including cardiovascular drug Tricor, which loses patent protection later in the year.

Abbott remains on track to split into two segments by the...
end of the year. While the split will not increase our fair value estimate, we do expect the breakup will give visibility to several undervalued business lines, which should lead to a quicker ramp in the company’s stock price to achieve our projected fair value.

Mar. 21, 2012  
No Fair Value Estimate Changes for Diagnostic Firms, Despite Negative Supreme Court Ruling  
The Supreme Court ruled Tuesday that two patents on a test sold by Prometheus Laboratories were invalid, sparking concern that patents on tests from other diagnostic firms--in particular Myriad Genetics --could be vulnerable to a similar fate. While nine of Myriad’s patents could also be reviewed by the Supreme Court this year, we think the firm’s broader protection on its tests makes it relatively insensitive to the Prometheus ruling and any potential direct ruling on Myriad itself, and we’re maintaining our fair value estimate for the firm as well as other companies in the diagnostics universe.

The court’s unanimous ruling was tied to Prometheus method-of use patents on tests to determine the proper dose of thiopurines for immunological disorders. The court believes that these patents were not based on novel or transformational qualities, but rather laws of nature that should not be patent-eligible. Focusing on Myriad, we think it’s difficult to draw direct comparisons to Myriad’s own patent headaches. Nine of Myriad’s patents could be reviewed by the Supreme Court later this year; however, these are composition of matter patents, and only represent a handful of the firm’s more than 500 patents issued in the United States. In addition, we think Myriad would have a much easier time demonstrating the novelty of its test, given that the firm is unable to determine whether a patient’s BRCA1 and 2 genes have risk-heightening mutations in less than 3% of cases, versus competitors that have a test failure rate closer to 20%-30%. This is part of the reason Myriad has been very successful with its colon cancer risk test Colaris, which does not have patent protection yet. It is seeing strong double-digit growth as the firm grows demand and increases its already dominant market share. So, while BRACAnalysis composition of matter patents begin to expire in 2018, we think the firm’s analysis of more than 1 million patients to this point has created a database that will take years to match, regardless of any patent decisions.

More broadly, we think the Prometheus ruling could set a precedent that hurts small diagnostic firms relying on a single test for profitability. Larger firms with diagnostic arms--such as Abbott or Roche--could potentially see some small benefits in the short run, as additional patent invalidations would allow them to broaden their menus on popular platforms. While some older tests offered by these firms may not meet the rising threshold for patent eligibility, broad patent protection is not the main source of their competitive advantages in diagnostics. For example, novel tests and complete menus are what help secure Roche’s leading market position.

Mar. 02, 2012  
Roche’s Actemra Data Continues to Impress, but Humira Still a Leading First-Line Choice in RA  
Roche reported top-line data from a Phase III study pitting its rheumatoid arthritis drug Actemra head-to-head against Abbott’s Humira, which indicated that Actemra was able to produce superior efficacy as measured by several endpoints. Because of the design of this trial, we doubt that it will have a dramatic impact on prescribing. However, we believe it points to Actemra’s ability to become yet another successful biologic blockbuster in this disease, and the
30%-50% of patients who don’t respond well to drugs like Humira remains the largest source for potential growth, in our opinion. We continue to see the drug attaining blockbuster sales north of $1 billion in 2013.

While details won’t be revealed until a later date, patients on Actemra in the ADActA trial saw superior reductions in disease activity to those on Humira over the six-month study. However, there are several reasons Actemra may not actually be a superior drug in practice. First, this was a relatively small, 300-patient study in difficult-to-treat patients who don’t respond to standard first-line therapy methotrexate, making it less representative of the broader RA population. In addition, the trial used Actemra’s highest dose and Humira’s standard dose (rather than the once-weekly dose often used in patients on monotherapy), which makes it difficult to compare efficacy.

Feb. 29, 2012

Abbott Strikes RA Deal With Galapagos To Create the Next-Generation Humira Drug

Abbott and Galapagos signed a collaboration agreement to develop Galapagos’ Phase II rheumatoid arthritis (RA) drug GLPG0634. While we don’t expect any changes to our fair value estimate for Abbott as the drug is still in early-stage development, we believe the compound potentially could help Abbott maintain its market-leading position in RA and other immunology diseases in the 2017-18 time period when its current immunology blockbuster Humira loses patent protection. The deal includes up to $1.3 billion in potential milestone payments to Galapagos based upon the successful completion of regulatory and commercial hurdles. Also, assuming successful development of the drug, Galapagos is eligible for a tiered double-digit royalty on sales. While data on GLPG0634 is only available from early Phase I and Phase IIa studies, the drug posted leading efficacy and minimal side effects. If the drug holds up in late-stage development, it could reach the market by 2017.

Jan. 25, 2012

Abbott Posts In-Line 4Q and Remains on Track to Split Into Two Companies

Abbott Laboratories reported fourth-quarter results and issued 2012 guidance in line with our expectations, and we don’t expect any changes to our fair value estimate. In the quarter, total sales increased 4% year over year, led by strong growth from immunology drug Humira. Earnings per share growth outpaced sales growth, up 11.5% from the prior-year period, as higher gross margins contributed the rapid growth. Abbott issued 2012 EPS guidance of $4.95-$5.05, in line with our expectations.

Humira continues to drive the sales growth for the pharmaceutical segment. The drug grew operationally 16%
analyst notes (continued)

versus the prior-year period. Based on its leading efficacy and side effect profile, we continue to expect double-digit growth for the drug over the next three years, despite new competition likely from Pfizer’s tofacitinib. Further, we expect Humira’s growth will help mitigate the 2012 patent losses on cardiovascular drug Tricor.

Outside the pharmaceutical group, the majority of Abbott’s segments posted steady gains. Second only to the drug group in size, the nutritional division generated 8% operational growth year over year. We believe the 2010 manufacturing issues for infant formula are largely behind the company and we expect steady growth for the division over the long term.

Efficiency improvements are driving margin improvement. As a percentage of total sales, operating costs fell more than 200 basis points year over year, largely driven by gross margin improvements. While we expect this trend to continue, we expect a deceleration in margin gains in 2012 because of the patent loss on the high-margin drug Tricor.

Abbott remains on track to complete its separation into two pieces by the end of the year. While we continue to believe the breakup will not likely cause a change to our fair value estimate, we expect it could increase investor attention to undervalued segments of the company, potentially causing the stock price to reach our fair value more quickly.
Abbott Laboratories ABT

Abbott manufactures and markets pharmaceuticals, medical devices, blood glucose monitoring kits, and nutritional health-care products. Products include prescription drugs, coronary and carotid stents, and nutritional liquids for infants and adults. Following the Advanced Medical Optics acquisition, Abbott also markets eye-care products. Abbott and adults. Following the Advanced Medical Optics coronary and carotid stents, and nutritional liquids for infants health-care products. Products include prescription drugs, Abbott manufactures and markets pharmaceuticals, medical

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At Morningstar, we evaluate stocks as pieces of a business, not as pieces of paper. We think that purchasing shares of superior businesses at discounts to their intrinsic value and allowing them to compound their value over long periods of time is the surest way to create wealth in the stock market.

We rate stocks 1 through 5 stars, with 5 the best and 1 the worst. Our star rating is based on our analyst’s estimate of how much a company’s business is worth per share. Our analysts arrive at this “fair value estimate” by forecasting how much excess cash—or “free cash flow”—the firm will generate in the future, and then adjusting the total for timing and risk. Cash generated next year is worth more than cash generated several years down the road, and cash from a stable and consistently profitable business is worth more than cash from a cyclical or unsteady business.

Stocks trading at meaningful discounts to our fair value estimates will receive high star ratings. For high-quality businesses, we require a smaller discount than for mediocre ones, for a simple reason: We have more confidence in our cash-flow forecasts for strong companies, and thus in our value estimates. If a stock’s market price is significantly above our fair value estimate, it will receive a low star rating, no matter how wonderful we think the business is. Even the best company is a bad deal if an investor overpays for its shares.

Our fair value estimates don’t change very often, but market prices do. So, a stock may gain or lose stars based just on movement in the share price. If we think a stock’s fair value is $50, and the shares decline to $40 without much change in the value of the business, the star rating will go up. Our estimate of what the business is worth hasn’t changed, but the shares are more attractive as an investment at $40 than they were at $50.

Because we focus on the long-term value of businesses, rather than short-term movements in stock prices, at times we may appear out of step with the overall stock market. When stocks are high, relatively few will receive our highest rating of 5 stars. But when the market tumbles, many more will likely garner 5 stars. Although you might expect to see more 5-star stocks as the market rises, we find assets more attractive when they’re cheap.

We calculate our star ratings nightly after the markets close, and issue them the following business day, which is why the rating date on our reports will always be the previous business day. We update the text of our reports as new information becomes available, usually about once or twice per quarter. That is why you’ll see two dates on every Morningstar stock report. Of course, we monitor market events and all of our stocks every business day, so our ratings always reflect our analyst’s current opinion.

The Economic Moat™ Rating
The Economic Moat™ Rating is our assessment of a firm’s ability to earn returns consistently above its cost of capital in the future, usually by virtue of some competitive advantage. Competition tends to drive down such

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**Morningstar’s Approach to Rating Stocks**

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**Our Key Investing Concepts**
- Economic Moat™ Rating
- Discounted Cash Flow
- Discount Rate
- Fair Value
- Uncertainty
- Margin of Safety
- Consider Buying/Consider Selling
- Stewardship Grades

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**Morningstar Research Methodology for Valuing Companies**

![Morningstar Methodology Diagram]

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Morningstar’s Approach to Rating Stocks  (continued)

economic profits, but companies that can earn them for an extended time by creating a competitive advantage possess an Economic Moat. We see these companies as superior investments.

Discounted Cash Flow
This is a method for valuing companies that involves projecting the amount of cash a business will generate in the future, subtracting the amount of cash that the company will need to reinvest in its business, and using the result to calculate the worth of the firm. We use this technique to value nearly all of the companies we cover.

Discount Rate
We use this number to adjust the value of our forecasted cash flows for the risk that they may not materialize. For a profitable company in a steady line of business, we’ll use a lower discount rate, also known as “cost of capital,” than for a firm in a cyclical business with fierce competition, since there’s less risk clouding the firm’s future.

Fair Value
This is the output of our discounted cash-flow valuation models, and is our per-share estimate of a company’s intrinsic worth. We adjust our fair values for off-balance sheet liabilities or assets that a firm might have—for example, we deduct from a company’s fair value if it has issued a lot of stock options or has an under-funded pension plan. Our fair value estimate differs from a “target price” in two ways. First, it’s an estimate of what the business is worth, whereas a price target typically reflects what other investors may pay for the stock. Second, it’s a long-term estimate, whereas price targets generally focus on the next two to 12 months.

Uncertainty
To generate the Morningstar Uncertainty Rating, analysts consider factors such as sales predictability, operating leverage, and financial leverage. Analysts then classify their ability to bound the fair value estimate for the stock into one of several uncertainty levels: Low, Medium, High, Very High, or Extreme. The greater the level of uncertainty, the greater the discount to fair value required before a stock can earn 5 stars, and the greater the premium to fair value before a stock earns a 1-star rating.

Margin of Safety
This is the discount to fair value we would require before recommending a stock. We think it’s always prudent to buy stocks for less than they’re worth. The margin of safety is like an insurance policy that protects investors from bad news or overly optimistic fair value estimates. We require larger margins of safety for less predictable stocks, and smaller margins of safety for more predictable stocks.

Consider Buying/Consider Selling
The consider buying price is the price at which a stock would be rated 5 stars, and thus the point at which we would consider the stock an extremely attractive purchase. Conversely, consider selling is the price at which a stock would have a 1 star rating, at which point we’d consider the stock overvalued, with low expected returns relative to its risk.

Stewardship Grades
Our corporate Stewardship Rating represents our assessment of management’s stewardship of shareholder capital, with particular emphasis on capital allocation decisions. Analysts consider companies’ investment strategy and valuation, financial leverage, dividend and share buyback policies, execution, compensation, related party transactions, and accounting practices. Corporate governance practices are only considered if they’ve had a demonstrated impact on shareholder value. Analysts assign one of three ratings: “Exemplary,” “Standard,” and “Poor.” Analysts judge stewardship from an equity holder’s perspective. Ratings are determined on an absolute basis. Most companies will receive a Standard rating, and this is the default rating in the absence of evidence that managers have made exceptionally strong or poor capital allocation decisions.