Alere

Tuesday, April 29th, 2014 @ 8:30 AM ET

1st Quarter Earnings Call

Doug Guarino:

Good morning and welcome to the Alere conference call to discuss our results for the quarter ended March 31st, 2014.

We are joined today by Ron Zwanziger, Chairman and CEO, Dave Teitel, CFO and Namal Nawana, COO.

Before we get to that discussion though, I would first like to draw your attention to the fact that certain matters discussed in this conference call will constitute forward-looking statements within the meaning of the US securities laws including statements about future organic growth, potential divestitures and anticipated reductions in costs. These statements reflect our current views with respect to future events or financial performance and are based on management's current assumptions and information currently available. Actual results and the timing of certain events could differ materially from those projected or contemplated by the forward-looking statements due to numerous factors, including without limitation, our ability to successfully complete planned divestitures, integrate our acquisitions and recognize the expected benefits of our restructuring and operational initiatives; the success of ongoing or potential product launches and product re-introductions; our ability to develop enhanced health information solutions through the integrated use of innovative diagnostic and monitoring devices and to recognize the expected benefits of this strategy; the impact of healthcare reform legislation; our ability to comply with regulatory requirements; the content and timing of regulatory decisions and actions, including the impact of the FDA Warning Letter and the OIG subpoena, as well as the impact of changes in reimbursement policy and budgetary constraints, both in the United States and abroad; and the risks and uncertainties described in our periodic reports filed with the Securities and Exchange Commission, including our Form 10-K for the year ended December 31, 2013, as well as in our Quarterly Reports on Form 10-Q. Our Company undertakes no obligation to update forward-looking statements.

Additionally, please note that during this call we may discuss non-GAAP financial measures. For each non-GAAP financial measure discussed, a presentation of the most directly comparable GAAP financial measure and a reconciliation of the differences between the non-GAAP financial measure discussed and the most directly comparable GAAP financial measure is available on the company's website at *www.alere.com/investors*

With that, let me turn the call over to Alere Chairman and CEO, Ron Zwanziger.

Ron Zwanziger:

Thanks, Doug, and good morning everyone.

As communicated on the 4th quarter call, we anticipated lower revenues in Q1 due to several factors, including the U.S. flu season having essentially concluded by the end of Q4, as well as a challenging contracting season for our Health Information Solutions business. However, also contributing to lower Q1 revenues was a larger-than-expected reduction in U.S. healthcare utilization, particularly physician office visits, resulting in lower testing volumes, principally in the infectious disease segment. The revenue challenges we recently experienced in the U.S. have been reported by others in the industry and we expect that many investors are already aware of the general trends. Aside from the U.S., our diagnostics business around the world performed well and demonstrated continuing organic growth.

As a result of our focus on global market development, as well as our diverse product portfolio, Alere is positioned to perform well even in challenging quarters such as Q1. A key focus for us must be to continue to maximize this potential. However, before returning to a discussion of this topic in more detail, I'd like to point out the progress we did make during the quarter in our other key initiatives.

A primary area of attention for us for several years now has been improving earnings predictability by strengthening our ability to respond rapidly to unexpected business challenges. In Q1 we achieved that goal, delivering cash-basis EPS of $0.55. This was achieved through strong cost control measures which were further tightened as the quarter progressed. On an adjusted-cash basis, R&D expense was flat with the 4th quarter and SG&A was reduced by approximately $5 million in non variable expenses compared to Q4.

Based on the complex near term revenue outlook in the U.S. we have very recently initiated a significant additional range of programs to improve effectiveness, which will help us in Q2 and will more fully support our results during the second half of the year. Namal will discuss these measures in further detail in just a few moments. We remain fully committed to our objectives laid out in the 3 point plan to investors; including the achievement of 28% SG&A as a percentage of revenue by the end of the year, and holding steady at that level for all of 2015.

In the first quarter we continued our recent trend of very strong cash flow, which is, in part, a result of increasing focus on operational excellence over the past year.

Another important achievement in the quarter was finalization of a key element in our plan to deleverage the balance sheet over the next few years. Today, we announced our intention to pursue an initial public offering in the U.K. of a new entity which will include several of our non-core businesses. After considering multiple options for the last year, we believe this is the most tax-effective and least dilutive method for us to unlock value from these assets, and the structure should provide us with ample flexibility in the future to de-lever with favorable terms and appropriate timing. Based on rules around the IPO process, our comments at this time must remain limited, beyond what appears in the release itself.

And now, let me turn the call over to Dave for a discussion of our reported financial results.

Dave Teitel:

Thanks, Ron, and good morning.

Adjusted net revenues for the quarter were $717.0 million compared to $739.9 million in Q1 2013. The effects of foreign currency translation decreased Q1 2014 adjusted net revenues by $2.6 million compared to Q1 2013.

Adjusted net product and services revenues from our professional diagnostics segment were $561.8 million in Q1 2014 as compared to $579.3 million in Q1 2013. The decrease in segment revenues relates principally to lower U.S. flu revenues which declined from $34.3 million in Q1 2013 to $7.3 million in Q1 2014 as a result of the shorter and less intense flu season experienced this year as compared to last. Excluding the impact of the change in U.S. influenza revenues and the impact on revenues from the U.S. meter-based Triage product sales, currency adjusted organic growth in our Professional Diagnostics segment was negative 1%. This growth rate was adversely impacted by the decrease in reimbursement rates that became effective on July 1, 2013 for our U.S. mail-order diabetes business. Excluding revenues from our U.S. mail-order diabetes business and considering the flu and Triage adjustments, the currency adjusted organic growth rate for the first quarter of 2014 was 4% for the remainder of our Professional Diagnostics segment, reflecting a 2% decrease in U.S. revenues, compared to the first quarter of 2013, offset by an 8% increase in our international business. The 2% decrease in the U.S. business principally relates to lower infectious disease revenues reflecting lower utilization levels during 2014 than during 2013. New products contributed favorably to our overall adjusted growth rate, with sales of CD4 products increasing from $3.1 million in Q1 2013 to $6.7 million in Q1 2014 and Epoc sales increasing from $4.7 million to $6.8 million for the same periods.

Net revenues from our Health Information Solutions segment were $123.7 million in Q1 2014 compared to $134.2 million in Q1 2013, reflecting growth in our patient self-testing business from $24.7 million in Q1 2013 to $27.2 million in Q1 2014, offset by decreases in all other areas of this segment as a result of the challenging contracting season for this group in the second half of 2013.

Net product and services revenues from our consumer diagnostics business segment were $26.4 million in Q1 2014 compared to $22.3 million in Q1 2013, reflecting continuing success from our Joint Venture with Procter & Gamble, driven particularly by the Clearblue Advanced Pregnancy Test with Weeks Estimator in the U.S.

Adjusted gross margin was 51.5% of adjusted net revenue in the first quarter of 2014 compared to 52.1% in the first quarter of 2013. The lower gross margin in the current period principally reflects the lower U.S. influenza sales and reduced mail-order diabetes reimbursement rates noted previously.

Adjusted selling, general and administrative expenses were $219.1 million or 30.6% of adjusted net revenues in Q1 2014 compared to $217.9 million or 29.4% of adjusted net revenues in Q1 2013. While disappointing as a percentage of revenue, adjusted SG&A decreased sequentially by $8.7 million from Q4 2013 as a result of $3.7 million of decreases in variable commissions and compensation on lower sales levels and $5.0 million of other savings from expense control measures. Adjusted research and development expense was $36.3 million or

5.0% of adjusted net revenues compared to $39.4 million or 5.3% of adjusted net revenues in Q1 2013.

Adjusted interest and other expense was $46.7 million in Q1 2014, compared to $56.7 million in Q1 2013. Adjusted interest expense, net of interest income was $51.1 million in Q1 2014 compared to $55.2 million in Q1 2013.

Our adjusted tax rate was 27.7% of pretax income compared to 34.0% in Q1 2013. We expect the tax rate for the balance of the year to be approximately 30%.

EBITDA for the quarter was $144.5 million, which includes deductions for restructuring charges of $7.2 million, $0.3 million of acquisition related expenses and $3.0 million of costs associated with potential dispositions. Cash flow from operations for the quarter was $105.9 million and capital expenditures were $27.5 million. As of the end of Q1, our net debt outstanding was $3.37 billion, a reduction of $81.4 million from our net debt level as of the end of 2013. Strong cash flow from operations coupled with principal repayments of just over $15 million contributed to this reduction. On an LTM basis, our Adjusted EBITDA with restructuring, acquisition and other costs added back, was $661.1 million resulting in a net debt to Adjusted EBITDA ratio of 5.1 times, compared with a net debt to Adjusted EBITDA ratio of 5.7 times at the end of Q1 2013.

I would now like to turn the call over to Namal.

Namal Nawana:

Thanks Dave. Despite the challenges experienced in the US market which Ron and Dave have already described, we are pleased to report another quarter of strong earnings per share for Alere. Our adjusted international organic growth rate of over 8% was driven by continued success in key geographies. We are pleased to report outstanding organic growth of 32.5% in Africa, driven by 116% growth of our CD4 platform and 63.5% growth in Malaria products. Our China business enjoyed organic growth of 15.6% and India grew 48%. We see continued rapid growth of these geographies for the remainder of 2014 and beyond. Latin America had a challenging quarter with only 1.5% growth, but this was largely due to an unfavorable diabetes comparable in Brazil that will not repeat beyond the quarter and also the lack of a dengue season this year, which was a key feature of strong growth in 2013. We anticipate a return to double digit growth in Latin America as the year progresses. In line with our previous comments on the fourth quarter call, we saw a return to growth in our European business in Q1 at 1.8% and we anticipate continued growth throughout the year.

In the Q4 earnings call we highlighted some technology platforms that we indicated would feature strongly in our growth in 2014. Global sales of our Epoc product grew 45% in the quarter and we project accelerating demand for this product as the year progresses. We saw many new major customers for our Afinion product in the quarter, with strong global growth of 17.6%. In addition to the growth of our CD4 platform in Africa, we have commenced a limited launch of this product in other Asian geographies including China, which will help contribute to continued accelerating growth.

We have seen a meaningful increase in the sales of our INRatio product in recent quarters as well as in our Alere Home Monitoring business. However, this slowed in Q1 as global INR sales were down slightly compared with the prior year. Additionally, although not within Q1, in April we initiated a voluntary recall of our Alere INRatio2 PT/INR Professional Test Strip in the U.S. due to an observed increase in the frequency of certain adverse events reported in association with discrepant readings with the device. We are replacing the INRatio2 test strips with an earlier version of the strip which we have continued to sell in certain segments of our U.S. market and which was not affected by the recall.

Our global professional INR revenues were $60.0 million in 2013 and $13.2 million in Q1 2014, of which $39.9 million and $8.2 million related to U.S. professional revenues. Included in our Q1 results were U.S. revenues of $6.5 million related to sales of the INRatio2 test strip, which is net of a $1 million reserve for product that may be returned as a result of the recall. We have begun working with our customers to supply them with the earlier version of the strip and thus far this has progressed well. Nevertheless, we anticipate an immediate impact of potentially several million dollars in revenue per quarter, for the next few quarters.

Triage global sales in Q1 were up 8.3%, with U.S. sales slightly up. This marks our first quarter of growth for Triage in the U.S. since we encountered supply issues in early 2012. It also comes ahead of a full return to the market of our Toxicology and SOB cardiac panel to the U.S. On the 4th quarter call we expressed optimism that at least one of these products would return in the first half of 2014. We were in fact able to bring back our Toxicology panel in March and saw initial sales of $600,000 in the quarter. We anticipate a full return to the market starting in Q2 and further accelerating as the year goes on, as our manufacturing output has substantially increased with stable yields. For our SOB cardiac panel product, we now anticipate a substantial return to the market in Q3, with potentially a limited return in June.

Our Alere I platform with flu A/B analytes was launched in Europe at the tail end of the flu season. Customer feedback has been excellent and we anticipate commercial success of the platform starting in Q3 of this year. Regulatory approval for the U.S. is still in process but progressing well. Upon completion of the 510k clearance process, we will turn to the CLIA waiver process which we hope to complete in time for the 2014-2015 season. Additionally, our clinical trials for a Strep A test running on this same platform have also gone well, which leaves us optimistic of both launching the product in the U.S. and delivering additional content in the near term.

Moving to our operational effectiveness initiatives, we continue to closely control expenses to deliver against our earnings plans. With a softening of the underlying sales volume in the U.S. in Q1, we have pro-actively taken substantial measures to reduce OPEX in Q2, including headcount reductions at several units throughout the company. These pro-active measures will help solidify our anticipated Q2 result and moreover contribute to our confidence around strong financial performance for the remainder of the year. We remain on track to deliver on our commitment of 28% SG&A rate in Q4 of this year even with an assumption of lower than originally anticipated U.S. sales.

Now let me hand the call back to Ron.

Ron Zwanziger:

Thanks Namal.

While the Q1 results did not fully reach our expectations, I hope it is clear that our cost reduction programs are progressing well and our predominant issue in the quarter was healthcare utilization in the U.S. rather than cost management or other issues.

Unfortunately, some of the low utilization rates that we are experiencing may persist and, as you have just heard, we are taking appropriate steps in response.

The path for us to meet our commitments for 2014 and beyond is to continue the progress we are making in cost management and debt reduction, while intensifying our focus on those drivers of revenue that are under our control. We expect that the second half of 2014 will bring several tailwinds to our organic revenue growth rate. We will see the first anniversary of the impact of the CMS reimbursement reduction on our diabetes business in the 3rd quarter, and we also expect to launch or introduce several major products in the U.S. at approximately the same time, including the continued reintroduction of additional Triage cartridges and the launch of our Alere i molecular platform. Finally, we are expanding manufacturing capacity to remove a supply constraint created by strong demand for the new markers we introduced on our blood gas & electrolyte analyzer over the year. All of these elements should contribute to an acceleration of U.S. revenues as the year progresses.

Our unique global positioning in near patient diagnostics and chronic condition management programs should continue to allow us to benefit from rapidly expanding markets outside the U.S., and underpin our accelerating revenue growth over the longer term. Alere has traditionally enjoyed strong organic growth in our diagnostics business as a result of our focus on high growth areas, such as Cardiology, Infectious Disease and Toxicology, and we expect to continue to benefit from this positioning globally. We remain focused on the targets we have laid out to our shareholders, and expect to deliver higher operating margins, improved free cash flow and increased earnings per share, in a sustainable and predictable manner as a result.

And now let me open the call up to questions. Operator?

Q&A

Ron's closing:

Steady improvements in our operational effectiveness, continued advancement in the development and launch of our new products, and meaningful progress in our deleveraging efforts should be taken as an indication that our long-term value creation strategy will enable us to generate sustainable success.

We are confident that this approach will continue to support improving financial performance and predictability of earnings, and strongly believe that our unique positioning to capitalize on the evolution of global healthcare will enable us to deliver long term value for all Alere shareholders for many years to come.

As always, I would like to thank you for your continued support and interest.

Thank you very much and have a good day.