Juliet Cunningham
Introduction & Safe Harbor

Good afternoon. Joining us for Alere's third quarter 2015 conference call is Namal Nawana, our CEO and President, and Jim Hinrichs, our EVP & CFO. Both Namal and Jim have prepared remarks and then we'll open the call for questions.

Our 3rd quarter earnings release is available on the Investor Relations page of our website. We will also post our prepared remarks on our website shortly after the conclusion of this call. As a reminder, this conference call is being webcast live on Wednesday, November 4, 2015. The audio replay of this call will be available on our website through November 11, 2015, and our prepared remarks and earnings presentation will be posted and archived on our IR page.

Before we begin, I'd like to inform you that we make forward-looking statements during this call, including, among others, statements with respect to anticipated future financial and operating results for the fourth quarter and for fiscal year 2015. Actual results and the timing of events could differ materially due to the risks and uncertainties described in our Form 10-K/A, Form 10-Qs and other SEC filings. We undertake no obligation to update forward-looking statements.

In addition, during this call we discuss certain non-GAAP financial measures. A reconciliation to the most closely comparable GAAP financial measures is included in our 3rd quarter earnings release or is posted on our website.

And now I'd like to turn the call over to Namal Nawana, CEO and President of Alere.

Namal Nawana
CEO Overview

Thank you, Juliet, and thanks to all of you joining us. Jim will go through our financials in detail shortly, but I'm going to focus on three key topics this afternoon:

- First, I'll discuss our 3rd quarter and year-to-date financial performance, focusing mainly on revenue composition;
- then I will review our business unit results, including major product and market drivers; and finally,
- I'll report our progress on key initiatives and plans that support Alere's success heading into 2016 and beyond.

Beginning with our 3rd quarter performance - revenue and non-GAAP earnings per share were below our expectations at $602 million and $0.54, respectively. Compared to the prior year period, revenue declined by:

- $33 million in foreign currency exchange
- $13 million in pain management and $8 million in INRatio
- $9 million from BBI revenue and lower sales into our consumer joint venture
- and $9 million in CD4 and malaria products sold in Africa

Organic growth declined to negative 1.7% during the 3rd quarter. Excluding pain management, organic growth was 0.3%. Despite these challenges, our core businesses had solid growth with increased sales in core platforms and services.

From a global region perspective – Latin America grew organically by 19% year-over-year, Asia Pacific grew 5%; Africa declined 12%; Europe declined 4%; and North America declined by 2%. Excluding pain management, North America grew by 1.2%. Jim will provide additional color on regional results later in the call.

Now, I'd like to review the business performance in each of our three core business units. Unless otherwise noted, all growth figures are on a constant currency basis, excluding acquisitions and dispositions.

Cardiometabolic

- Beginning with our Cardiometabolic business, which grew organically by 4.3%. Q3 revenue was $208 million and was driven by 15% growth in Asia and 2% growth in North America.
- From a product perspective, Afinion continues to perform well with approximately 1,425 placements during Q3, including large hospital placements in North America. Overall, Afinion A1C grew 26% globally in Q3.
- epoc grew 23% as we fulfilled backorders and began adding new customers and expanding our presence further into the Emergency Dept. and other parts of the hospital.
- Patient self-testing grew 12% and meter-based Triage grew in excess of 10%. This growth was offset by lower INRatio and LDX cholesterol product sales.

Infectious Disease

- Our Infectious Disease business generated Q3 revenue of $164 million, a 3.9% decline in organic growth. The decrease in organic growth compared to the prior year period was driven primarily by a 7% decline in Europe and a 13% decline in Africa.
- Africa declined due to lower CD4 and malaria sales. In the case of CD4, the WHO recommended that doctors and clinicians prioritize viral load to monitor the success of anti-retro viral therapy, but also acknowledged the need to include CD4 if viral load is not routinely available and also to help stratify risk. Given that point of care CD4 is lower cost, more accessible and it provides connectivity through the cellular networks, we continue to believe that our Pima CD4 remains a key tool to improve health outcomes. The change in guidelines has created some uncertainty in the CD4 market, but we expect CD4 sales to return to growth in 2016. Secondly, we see many opportunities to convert lab-based CD4 testing to point-of-care in the HIV market.
- Malaria sales in Africa have also been impacted by the timing of tender shipments, which tend to fluctuate, and also continued pricing pressure. While we don't see pricing pressure abating in the near-term, we have new malaria innovations in the pipeline that we believe will help mitigate the current pricing environment and deliver better economics in the future.

- Turning now to flu - global flu sales had a solid quarter with organic growth of 18% vs. the prior year period. Total global flu sales in Q3 were $20 million, including $5 million in Alere i.
- The focus of our salesforce in Q3 was to get Alere I in place ahead of the flu season, and they did that admirably. We have now achieved more than 2,800 instrument placements around the world year to date and we believe we will exit the year with greater than 4,000 instrument placements. This sets the stage nicely for future kit revenue, whether it's for flu, strep or any of the future analytes.
- I'd like to take this opportunity to recognize the Alere i team for a job very well done. With their hard work, we have added large hospital groups and networks to our Alere i customer roster and we estimate that competitive conversions were 43% year to date. In addition, we estimate that about 20% of new Alere i customers were doctors and clinicians who previously didn't test for flu but are now realizing the benefits of rapid molecular diagnostics at the point of care to improve patient health outcomes.
- We've had a very positive customer response, and we believe that we are well positioned to lead in point-of-care molecular tests on our multi-analyte platforms. Importantly, we have now completed the automation of our Alere i manufacturing line and this, coupled with scaling volumes, will help substantially lower our COGS in future quarters.
- Just last quarter we added Strep A to the menu with the first sales in Q3 - and we now expect Alere i Strep sales to ramp steadily. Also during Q3 we received clearance to use our Alere i flu assay with viral transport media, and this additional claim enables us to better serve our hospital customers. In addition, we expect to enter clinical trials to expand the Alere i menu with RSV in the 4th quarter. We are also making excellent progress on *C. difficile* and chlamydia/gonorrhea as new analytes.
- Global HIV sales grew 2.9% driven by solid growth in Asia Pacific and strong demand for our Determine Combo products in the US.
- In addition, we've shipped over $1 million in Alere q products over the past two quarters and are excited about the opportunity for this point-of-care molecular platform.

Toxicology

- Moving now to our Global Toxicology business - Q3 revenue was $163 million, a 3% year-over-year decrease that was driven by pain management, which declined 63% from the prior year period. Excluding pain management, our core Toxicology revenue grew by 6% during Q3, which represents 10 consecutive quarters of organic growth.
- Our efforts to stabilize pain management have not yielded the desired results. Despite Q3 being the first quarter to show stabilized lab volumes, we continued to have payment pressure. The national payer we contracted with in July has not yet ramped volume and other contracting efforts have stalled as the market awaits a final pricing determination from CMS. As you may be aware, CMS released its Preliminary Determination for the Clinical Lab Fee Schedule, but the recommendations will not be finalized until November.
- This remains a very turbulent period in the pain management market segment, as evidenced by continued pricing pressure and numerous competitors exiting the market. We have closely monitored this business and have cut costs wherever possible. At the same time, we have evaluated strategic alternatives for pain management throughout the year and will continue to do so. Pain management now represents less than 5% of total Toxicology revenue and less than 1% of Alere revenue.
- Switching gears to our Core Toxicology business, organic growth drivers included our global Reagents business, which increased by 13% and Employer Services, which grew 8% year-over-year.
    - In our Reagents business, we achieved two additional 510(k) clearances during Q3, including EDDP – a methadone metabolite, and PCP, a drug of abuse. As you recall, we previously cleared six drugs, bringing our year to date clearances now to eight. We continue to pursue key clearances to improve our portfolio and now have the building blocks to enter the Regulated Workplace and Hospital markets. We will approach this new market for Alere in Q4 and expect a strong launch with key laboratory and trade partners in early 2016.

- In Employer Services, we expanded our reach to more than 3,700 e-screen enabled clinics, adding approximately 120 new clinic partner locations. We signed approximately $2 million in national account wins with large employers and 3rd-party administrators, which we are working to on-board in Q4.

- Finally, in July we announced the acquisition of US Diagnostics, a leading provider of drug tests in the US. The integration has proceeded well and we are already seeing the anticipated financial returns from this acquisition.

• Our Toxicology team is looking forward to an active 4th quarter as they implement multiple product and customer wins, and we still expect to return to overall revenue growth in Q4.

• Lastly, I want to take a step back and share some thoughts with you on our progress to date and priorities going forward because in times of volatility it's easy to lose sight of the bigger picture. We <u>are</u> in the process of transforming Alere to be a world-class global enterprise.

• We have sharpened our focus on core products, removed more than $100 million in costs and reported three consecutive quarters of organic growth prior to the 3rd quarter. As you can see on Slide 4, the operational discipline being exerted by the organization is evident when analyzing the trailing 12-months operating expense trends which normalize for seasonal revenue variance.

• Although we faced significant revenue challenges in Q3, we demonstrated our ability to exercise strong expense management discipline which contributed to a 54% increase in non-GAAP adjusted EPS compared to the prior year period. Year-to-date, we delivered non-GAAP adjusted EPS of $1.62 per diluted share from continuing operations and organic growth of 1.3%.

• As we continue to focus our business on rapid diagnostics, we are pleased to report that we are on track to close the BBI divestiture this quarter and we remain committed to strengthening our balance sheet and redeploying capital appropriately. We continue to pursue the divestiture of SPD, our consumer joint venture with P&G, and the litigation we discussed previously is now progressing in a positive direction for SPD. Based on these developments, we expect to move forward with the SPD disposition in 2016. We also continue to pursue the divestiture of other non-core assets to reduce our debt.

- With that as a backdrop, I'll provide our revised guidance. Based on our current business outlook, we expect 2015 revenue to be in the range of 2.48 to 2.50 billion dollars and non-GAAP adjusted EPS of between $2.20 and $2.25 per diluted share. Full year adjusted non-GAAP EPS growth year on year would, therefore, be in the 19 to 22% range.
- Finally, looking longer term, we believe the financial thesis for Alere remains fully intact. We've done the checks and firmly believe that our markets are still growing organically in the mid-single digits and we fully expect to return the company to organic revenue growth in Q4 and next year. Further, between product mix and a multitude of margin enhancement projects, there are significant, multi-year leverage opportunities throughout our P&L.
- And now, I'll turn the call over to Jim.

Jim Hinrichs
Financial Overview

- Thanks, Namal, and good afternoon everyone. I've got two topics I want to cover today – first, I'll review the 3rd quarter financials, providing color and variance drivers, and then I'll discuss some of the key financial initiatives that are underway to improve long-term profitability at Alere. But before I get into the details, I want to give you what I think are the three key financial takeaways from the 3rd quarter:
    - First and most obviously, 3rd quarter revenue and, therefore, earnings were below our expectations. The primary drivers of this revenue shortfall were misses in Africa, Asia and a few of our non-core, soon-to-be-divested businesses. We understand these misses and do expect a bounce back in the 4th quarter which I'll describe shortly.
    - Second, the restructuring and cost base improvements that the team instituted last year continue to yield measurable and visible results, and we expect that trend to continue into the 4th quarter, with operating expense discipline driving strong leverage to the bottom line for the full year. This phenomenon will persist despite lower than expected revenues.
    - Finally, we have reset our 4th quarter and full year 2015 expectations, which are very achievable and we're pushing very hard to finish the year strong with positive momentum going into 2016.

So, moving to the 3rd quarter numbers, please note that I'll be discussing non-GAAP results unless otherwise specified. For comparison purposes, you'll find a full reconciliation from GAAP to non-GAAP in our 3rd quarter 2015 press release on the Investor Relations section of our website.

Net revenue for the 3rd quarter was $602 million, compared to $649 million in the prior year period. The 7.3% or $47 million year-on-year decrease was primarily driven by negative foreign exchange impact of $33 million; a $13 million decrease in pain management; $9 million in lower sales of BBI and sales into our Consumer joint venture; and $9 million in CD4 and malaria sales in Africa. Partially offsetting these declines were year-on-year increases in cardiac markers, patient self-testing, Afinion, epoc and core Toxicology.

Looking beyond the year-on-year variances, I suspect many are asking what changed for Q3 versus what we expected 90 days ago. As I noted in my summary comments, the shortfall versus our recent expectations came primarily from Africa, Asia and select non-core businesses. More specifically, in Africa, as Namal mentioned, changing CD4 guidelines as well as delayed tenders and price competition in the Malaria market hurt 3rd quarter sales. We <u>do</u> expect Q4 to be a much stronger number in Africa with CD4 and Malaria products bouncing back a bit and sales of HIV products filling the rest of the gap. With respect to Asia, the shortfall in China was driven by economic volatility which caused some distributor de-stocking. Korea had the hangover effect of the MERS outbreak, which dampened overall utilization in that country. Notwithstanding those issues, we expect Q4 to be a much better overall number in Asia, with China, Japan and India leading the way. Finally, looking at our non-core or "Other" revenue, the shortfall was primarily due to sales into our consumer JV, which carry very little margin, and BBI revenue declines. As you know, this business is scheduled to be divested later this month.

Continuing with Q3 revenue - Professional Diagnostics revenue of $580 million was comprised of $208 million in Cardiometabolic Disease; $164 million in Infectious Disease; $163 million in Toxicology; and $45 million in Other revenue, which reflected the divestitures of Bionote, DGP and Alere Analytics. Consumer Diagnostics revenue was $19 million and License and Royalty revenue was $3 million in Q3.

From a geographic split standpoint, 59% of our revenue in the quarter came from North America, 17% from Europe, 14% from Asia Pacific and 10% from rest of world.

Looking at gross margins - adjusted gross profit was $293 million with 48.5% gross margin in Q3, compared to $324 million with 49.8% gross margin in the year ago period. The two biggest headwinds by far continued to be foreign exchange, especially the significant negative currency moves we saw in Latin America and Asia, and product mix - again, primarily due to lower contribution from the high-margin Pain Management business. These are the same trends we've been discussing all year. Compared to the 2nd quarter, gross margin remained relatively stable sequentially.

Looking at expenses, adjusted operating expenses totaled $187 million, or 31.0% of net revenue, down 10% year on year. Adjusted operating expenses were comprised of $27 million in R&D and $160 million in SG&A, which were 4.5% and 26.5% of revenue, respectively. The modest increase in R&D from the 2nd quarter run-rate was expected and reflects continue build out of project management capability and investment in our critical projects. SG&A was down quarter over quarter, primarily as a result of lower incentive compensation expense and continued cost controls around discretionary spend on things like travel and expenses, as well as consultants.

Moving down the P&L, adjusted operating income was $105 million in the 3rd quarter, a 10% year-on-year decline and adjusted operating margin in 3rd quarter was 17.5% of net revenue.

Adjusted interest and other expense was $38 million in Q3 versus $60 million last year, driven by lower interest expense from debt pay down and our June refinancing, as well as realized foreign exchange losses last year that did not repeat this year.

Adjusted EBITDA in the 3rd quarter was $135 million, and our 3rd quarter adjusted tax rate was 28.4%, which was largely in-line with our expectations and significantly below last year's rate.

Finishing up the P&L, thanks to the lower interest and tax expense, adjusted net income from continuing operations increased 61% year-on-year to $48 million, or $0.54 per diluted share, with diluted common shares outstanding at the end of the quarter of 100.8 million.

Turning to the balance sheet and cash flow, as of September 30th we had $479 million in cash and $2.7 billion of debt, net of cash. Operating cash flow for the 3rd quarter was $105 million and free cash flow was $84 million. This is an improvement over the 1st half of the year as a result of higher net income and a continued focus on better working capital management. We're still a bit behind last year, and we continue to push to get to our full year free cash flow number even with last year's number of approximately $120 million. As a reminder, this is a high bar as it includes cash flow from discontinued operations of approximately $30 million. Finally, as Namal said, we expect BBI to close shortly which should bring in another $117 million of cash in the 4th quarter.

Looking toward at the 4th quarter and full year, Namal provided our revised guidance range of approximately $2.48 to $2.50 billion dollars on the top line and between $2.20 and $2.25 non-GAAP adjusted earnings per diluted share. Although we only provide annual financial guidance, at this stage in the year with only one quarter remaining, it seems reasonable to do the math and tell you that our full year guidance implies 4th quarter revenue in the range of $640 to $660 million and non-GAAP adjusted earnings per diluted share of 59 - 64 cents.

Although these results are a step up from Q3, which reflects normal seasonality at Alere, they are clearly achievable and we feel we've got good line of sight to them. We are approaching the 4th quarter aggressively to help ensure that we achieve these results. More specifically, both Namal and I are personally taking steps to ensure resources and direction to the leaders of key markets that will make or break Q4. In addition, we're proactively targeting discretionary spending with targeted reductions in travel and expenses, outside consulting, and non-revenue generating new hires.

Now as mentioned earlier, I'd like to finish by sharing some thoughts on the longer term underlying cost drivers and the potential for <u>continued</u> enterprise-wide profit improvement. Last quarter, I said that we see the potential to systematically remove tens of millions of dollars in costs over time as we simplify Alere and manage the Company as one global enterprise. Since then, we've continued to work on these opportunities which will come through strategic initiatives around: pricing, global procurement, IT, corporate infrastructure simplification, our internal operating and service delivery models, better treasury and tax planning, and many other things.

These are obviously multi-year initiatives, but we've already realized some small "quick wins" in a number of these: We've built capabilities and made changes to the way we look at pricing and discounting. We hired a chief procurement officer and initiated a true global strategic sourcing effort, we consolidated and now have access to tens of millions of dollars of cash, and we brought in a new Tax leader and team to build our internal tax accounting and planning capabilities, which we expect will drive better long-term results.

We expect these things to contribute meaningfully to our results in 2016 and beyond. Most importantly, we've initiated work on a broader corporate-wide simplification project designed to find complexity and drive it out of the organization. We believe this effort will benefit all of our stakeholders by making it easier for our customers to do business with us and, ultimately, drive a more profitable enterprise for our shareholders. We're in the early stages of this journey, and we plan to share longer-term targets and metrics as a result of this work in early 2016.

Finally, I want to take the opportunity to thank all the Alere employees around the globe for their hard work in helping us achieve the vision for Alere. Without the great people here, none of what we're trying to do would be possible.

With that, we can now open the line for questions.

Q&A session

Namal Closing Remarks

In closing, this was not the revenue quarter that we were planning, but continued strong operating discipline drove a solid $0.54 of adjusted non-GAAP earnings per share. Most importantly, we have clear line of sight to restore organic growth in Q4 and accelerate growth to at or above market growth levels in 2016.

Thank you for your continued interest in Alere and good evening.