QUIDEL FIRST QUARTER 2019
CONFERENCE CALL SCRIPT
Wednesday, May 8, 2019
2:00 p.m. PT/ 5:00 p.m. ET

OPERATOR:

Ladies and gentlemen, thank you for standing by.

Welcome to the Quidel Corporation first Quarter 2019 earnings conference call. At this time all participants are in a listen-only mode. Later, instructions will be given for the question-and-answer session. If anyone has difficulty hearing the conference, please press *0 for operator assistance.

I'd now like to turn the call over to Mr. Ruben Argueta, Quidel's Director of Investor Relations. Please go ahead.

Ruben Argueta

Thank you, Operator. Good afternoon everyone -- and thank you for joining today's call. With me today is our president and chief executive officer, Doug Bryant and Randy Steward, our Chief Financial Officer.

Our first quarter 2019 earnings release is now available on ir.quidel.com, our Investor Relations website. We will also post our prepared remarks on the Presentations tab of our IR website following the conclusion of this call, on May 8th, for a period of 24 hours.

Please note that this conference call will include forward-looking statements within the meaning of Federal securities laws. It is possible that actual results and performance could differ significantly from these stated expectations. For a discussion of risk factors, please review Quidel's annual report on Form 10-K, registration statements and subsequent quarterly reports on Form 10-Q, as filed with the SEC.

Furthermore, this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, May 8, 2019. Quidel undertakes no obligation to revise or update any statements to

reflect events or circumstances after the date of this conference call, except as required by law.

Today, Quidel released financial results for the three months ended March 31, 2019. If you have not received our news release, or if you would like to be added to the company's distribution list, please contact me at 858-646-8023.

Following Doug's comments, Randy will briefly discuss our financial results. Then, we'll open the call to your questions.

I'll now hand the call over to Doug for his comments.

DOUG BRYANT

Thank you, Ruben, and good afternoon everyone. The three topics that I would like to cover with you today are first, our financial performance, both for the full year and for the quarter; second, the status of products in development; and, finally the status of the Danaher litigation. And of course, I'm happy to answer your questions as well, following Randy's remarks.

About our financial performance, I'll begin by saying that we had another good quarter, consistent with our internal expectations, and, importantly, are in very good shape to achieve the goals for the full year that we've communicated previously. There is a gap with analyst consensus for Q1 that we will address today, but again, our financial performance for the period was fine. Here are a few details on our expectations for the full year and on the recent quarter.

For the year, there is good news. Our goal for the year, upon which our management team is accountable to our board of directors and its incentive is based, is unchanged. With Q1's performance, we expect to meet or exceed our 2019 Annual Operating Plan. Flu was better than we expected, and China cardiovascular revenue strength offset cardiovascular softness in the United States, most of which appears to be due to timing. Last year during the analyst day meeting in April, we expected revenues of "up to $520 million" as our target. Later in the year, we raised it to "over $520 million". This year, in early May, with Q1 behind us, we believe that a target of $535 million on a constant currency basis seems appropriate. Absent Flu and rapid strep, this would represent 8% revenue growth, year over year.

For Q1 our total revenue performance, at $150 million on a constant currency basis, was spot on our Annual Operating Plan. There was $2.2 million in unfavorable FX due almost entirely to the cardiovascular business, which brought our net revenue to $148.0 million. Now that we are off the TSA agreements in Europe and China, we have implemented a hedging policy, and Randy can walk you through the details on what we are doing moving forward during the Q&A.

In Q1, the two larger drivers to our financial performance were the respiratory disease products and cardiovascular, as expected. For Influenza, I think it's safe to say that most of us overcalled the year-over-year downside. Our influenza revenue for the quarter was $47.2 million, which makes Q1 2019 our second highest quarter ever for flu, behind last year's monster Q1, and better than we planned by $5 million.

Getting quarterly flu right has always been a challenge, and now, because of the magnitude of the cardiovascular franchise, forecasting this business well is equally important. We advised our shareholders to expect $276 million in revenue for the year, and an overall growth rate for the year of just under 4%, driven by introductions in the back half of the year of the new toxicology panel globally and high sensitivity

Troponin in Europe. We said, further, that they should expect to see from $64 million to $69 million in the early quarters, given variability in distributor orders in any given quarter. In Q1 2018, last year's first quarter, we did $68 million, which included a $1.5 million swing between the two quarters. In other words, we did $66.5 million. We advised shareholders on several occasions that the ongoing cardiovascular business, all things normalized, "felt" more like $65 million per quarter. For Q1 2019 cardiovascular revenues were $68 million in constant currency, or $65.9 million with $2.1 million in unfavorable FX. We did what we said we would do in any given quarter before the new products are launched and are still comfortable with our overall full year revenue forecast, assuming a normal Q4 respiratory season start.

Non-GAAP EPS for the quarter, was $0.91. On a constant currency basis, it was $0.94, which was precisely on our Annual Operating Plan. Two unplanned factors had a negative impact on EPS. First, gross margin in the quarter on legacy rapid diagnostic products was depressed due to factory absorption at our McKellar facility, where those products are still made, as we burned through influenza inventory that we were carrying over from Q4. In addition, cardiovascular price was lower due to mix, as sales in China at lower prices offset sales in the US at higher prices. And second, we had unplanned, short-term spending

increases in a couple areas: Savanna expenses with third parties involved in cartridge and instrument manufacturing, and litigation expenses. If not for the expense increase, EPS would have been $0.03 higher.

Regarding product development, I will be brief, and you can ask for clarification if you like during the Q&A. Our R&D teams had another very productive quarter, and the news here on this topic is again very positive. First, Strep 98 is in clinical trials in the US, and the data thus far are encouraging. Second, the six Sofia GI products expected in the next 12 to 18 months are progressing nicely, and the Sofia C. diff toxin/GDH product performance in beta trials was outstanding. Third, the technology that will enable multiplexing on Sofia test cartridges has proven to be robust and we should be able to manufacture in large volumes; therefore, Sofia Tier 2 Lyme (which will replace western blot as a confirmatory assay) and Sofia RVP look increasingly possible. And finally, assay development for six Savanna mini-panel multiplexed cartridges is on schedule, and we are at last getting to cartridge design freeze in advance of instrument system integration, and a firmer timeline.

Regarding the Danaher/Beckman litigation matter, I will also be brief, but will not be taking questions today. Most recently, the Court of Appeal issued an order agreeing to hear our writ petition on the merits of the case and has stayed the trial court's December 7th order. We are pleased that the court of appeal has agreed to hear the merits of our challenge of the trial court's decision. The timing for hearing oral arguments is likely to be this summer or early fall, with a decision from the court to follow no more than 90 days from when the court hears the matter. Our position remains unchanged. We view Beckman's claims as meritless, and in opposition to Beckman's longstanding strategy of honoring the Supply Agreement with its previous partners, Alere and BioSite, over the last 15 years. We remain confident in our position and confident in the outcome of the matter on appeal and ultimately at trial, as the matter progresses.

In summary, we had another solid quarter, and we achieved what we said that we would. I must add that I'm pleased with our overall forecasting accuracy. But in fairness, having more levers than just influenza helps significantly, and it should get increasingly easier as we continue to grow, both organically and through acquisition. I've said this so many times over the last year that it's beginning to feel redundant, but our focus as an organization is on leveraging several assets - our

significant Sofia installed base and brand; our cardiovascular and toxicology franchises; our R&D skill, talent, expertise and know-how; our manufacturing and automation competence; our global infrastructure and footprint; and our customer and distributor relationships - to the greatest extent possible.

Randy….?

RANDY STEWARD

First Quarter Financial Results

Thank you, Doug. Good afternoon everyone. As we reported earlier today, total revenues for the first quarter of 2019 were $148.0 million dollars, as compared to $169.1 million dollars in the first quarter of 2018, a decrease of 13%. On a constant currency basis, revenue would have been $150.2 million dollars in the quarter. The negative currency impact of $2.2 million dollars was mostly driven by weakness in the Euro and Chinese Yuan. From a product perspective, $2.1 million dollars of the $2.2 million dollars impacted Cardiac revenue. As expected, the year-over-year decline in total revenue was due to an 18% decline from the Legacy business, due in large part to the record flu season that we experienced in the record first quarter of 2018.

Beyond flu, we also saw revenue declines from other seasonal tests that trend with a stronger or weaker respiratory season, such as Strep A and RSV.

Moving on to the major product categories, Rapid Immunoassay revenue declined 23%, or $18.2 million dollars, from the first quarter of 2018, primarily due to a $17.4 million-dollar difference in flu revenue from Q1 2018. Total flu revenue was $47.2 million dollars, above our internal estimates. Sofia revenue was $42.9 million dollars, as compared to $58.1 million dollars in Q1 of the prior year, and QuickVue revenue was $18.4 million dollars, as compared to $21.4 million dollars in Q1 of 2018. Consistent with a weaker respiratory season than in 2018, within this immunoassay business, Strep A declined 10% and RSV declined 2%. Rapid Immunoassay unit inventory at distribution is down 25% from the same quarter last year, and down 32% sequentially. Specific to flu, inventories are down 36% versus last year's first quarter.

In the Cardiac Immunoassay category, revenue totaled $65.9 million dollars in the quarter versus $68.4 million in the same period last year. As mentioned previously, FX had a $2.1 million dollar negative impact on Cardiac revenue, and on a constant currency basis, revenue was $68.0 million, just slightly below the reported number last year. Triage

revenue was $35.6 million dollars, which declined 10% from the first quarter of 2018. On a constant currency basis, Triage revenue was down 6% versus last year. Regionally, Triage saw revenue declines in North America, EMEA and Latin America, which was partially offset by 6% growth in China. On the Beckman BNP side, revenue increased 4% over the first quarter of 2018 to $30.3 million. On a constant currency basis, BNP was up 7%. Regionally, China was the biggest contributor to revenue growth, which was partially offset by revenue declines in North America and the EMEA region.

Overall, we believe that 4% growth from Cardiac is achievable, and is partly contingent upon revenue contribution from newly-launched TriageTrue troponin in Europe, and the anticipated launch of our next generation Toxicology assay.

Revenue in the Specialized Diagnostic Solutions category decreased 7% in the first quarter of 2018 to $13.9 million dollars, primarily due to a decrease in our respiratory and general virology cell culture products.

Our Molecular Diagnostic Solutions category increased 12% in the quarter to $5.7 million dollars, due to 24% growth from Solana assay revenue.

Gross Profit in the first quarter of 2019 decreased $15.3 million dollars, primarily the result of lower sales of Rapid Immunoassays in the quarter. Gross margin in the first quarter of 2019 was approximately 61%, as compared to 63% in the first quarter of 2018. Lower factory absorption related to lower production impacted the legacy business, while currency and geographic mix had a negative impact on the Cardiac gross profit and margin. For the full year, we are estimating gross margin improvement over 2018.

R&D expense increased by $1.3 million dollars in the first quarter as compared to the same period last year. This increase is due to the incremental expense associated with the Savanna molecular diagnostic platform and Sofia gastrointestinal assays. This was partially offset by decreased spend in the Triage business. We believe that our R&D expense is tracking to our expectations, and estimate that for the year the R&D spend will be in the range of $52 million dollars to $55 million dollars.

Sales and Marketing expense was $29.6 million dollars in the quarter, an increase of $1.0 million dollars, as compared to the first quarter last year. This increase was largely due to higher word-of-mouth marketing

and product promotional costs than in the prior year. For the full year 2019, we continue to expect Sales and Marketing expense to be in the range of 50 to 100 basis points lower than last year, as a percent of revenue.

G&A expense increased by $2.9 million dollars in the quarter, primarily due to increased infrastructure investments to support our global business, and increased professional fees.

Acquisition and Integration costs in the first quarter were $2.8 million dollars, as we completed the integration for China and Italy.

Interest expense for the quarter was $4.6 million dollars, and includes $1.0 million dollars relating to the Convertible Senior Notes, $0.5 million dollars relating to the Senior Credit Facility, and $2.3 million dollars relating to the deferred and contingent consideration associated with the purchase of the BNP business. The $3.3 million decrease in interest expense over last year was due to the reduction in debt of approximately $196.6 million dollars over the last twelve months, and this includes the deferred and contingent consideration.

In the quarter, we recorded $1.7 million in income tax expense. The low effective tax rate for the quarter is due to discrete tax benefits for excess stock-based compensation expense. We believe our effective tax rate for 2019 should be in a range of 19% to 21% of pre-tax income before consideration for discrete tax items. The impact of the 2017 Tax Cuts and Jobs Act regulations are yet to be finalized, and will impact where we fall in this range.

We continue to strengthen our balance sheet. In the quarter, we generated $28 million dollars in positive cash flow after spending $5.0 million dollars in capital expenditures, and paid off another $20.0 million dollars on the revolving Senior Credit Facility. In the quarter, we had depreciation of $4.7 million dollars and amortization of $7.0 million dollars. As of March 31, 2019, the company had $56.9 million dollars in cash on the balance sheet, $58.5 million dollars in principal amount outstanding relating to the Convertible Notes, and $33.2 million dollars outstanding on the Revolving Credit Loan. Additionally, in April we made our second $48.0 million-dollar payment to Abbott, and the outstanding principal balance on deferred and contingent consideration for the acquired Cardiac assets is now approximately $184.0 million dollars.

And with that, we conclude our formal comments for today. Operator, we are now ready to open the call for questions.

Q&A

OPERATOR

That is all the time we have today. Please proceed with your presentation or any closing remarks.

DOUG BRYANT

Thanks everyone for your support and for your interest in Quidel. We had another great quarter, and I believe that we are well-positioned to achieve our growth objectives. Take care, everyone.

OPERATOR

Ladies and gentlemen, we thank you for your participation, and ask that you please disconnect your lines. Goodbye.