QUIDEL FOURTH QUARTER 2018
CONFERENCE CALL SCRIPT
Wednesday, February 13, 2019
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OPERATOR:

Ladies and gentlemen, thank you for standing by.

Welcome to the Quidel Corporation Fourth Quarter and Full Year 2018 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 fourth quarter and full year 2018 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 February 13th, 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, February 13, 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 and full year ended December 31, 2018. 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. Thanks for listening in on the call.

We have a lot to do this year, 2019, and there are many great, exciting opportunities ahead of us, so I won't spend too much time after today looking in the rearview mirror. Having said that, Q4 2018 was a solid quarter for us and 2018 overall was extraordinary. Early in the year, at our analyst day in Chicago, we communicated several milestones, several expectations for the year. We said, first, that our commercial

leadership and their teams could fully absorb the larger sales and marketing responsibilities, establishing a solid revenue baseline for the acquired Triage products, while continuing to grow our legacy immunoassay and molecular businesses as we had in the past. We said that we would do this by recruiting and installing the necessary people and infrastructure internationally but would not need to add significant resources for the US. We said that we believed that we would reach $250 million for the combined Triage businesses globally; instead, we did $267 million in revenue for the year. We said that we would deliver 10% in revenue growth for the base, driven by new Sofia and Solana placements; instead, we did 11%. In terms of the integration of the newly acquired assets, we said that by the end of the year 95% of order to cash for the Triage businesses would be under our control, and that we would achieve $10 million in annual run-rate savings. By the end of Q1, 2019, when the China business goes live, we will be at 96%, and at the end of 2018 our cost savings run-rate was at $13.3 million. And finally, in terms of financial performance, we said that we planned to reach 32% in terms of EBITDA as a percentage of revenue for the year, and that with cash and through a share exchange for our convertible debt, we intended to lower our leverage ratio to below 1.5X. For 2018, EBITDA was 33% of revenue, and our leverage ratio at year end was at 0.9X. In summary, each of the key metrics that

we announced at our analyst day was accomplished, except for a minor delay with bringing China on board and under our complete control.

Before moving off 2018, allow me to mention a few other notable achievements. First, we placed nearly 10,000 Sofia instruments net of replacements. Sofia truly is a flagship product for us and the franchise is doing extremely well.

Second, the molecular franchise is gaining traction, with Solana reagent kit revenue doubling year over year, helped greatly by the newer products, HSV/VZV, and C. difficile.

And third, our R&D and regulatory teams haven't slowed down at all. Three products, Sofia Vitamin D, Sofia Lyme (with the European bugs added), and TriageTrue High Sensitivity Troponin I, each received the CE Mark and are cleared for sale in Europe. Four products, the CLIA waived, WB fingerstick version of Sofia Lyme, the serum version of the Lyme test, Solana Bordatella complete, which includes both pertussis and para-pertussis, and QuickVue Influenza, which meets the FDA's reclass guidelines, were each FDA cleared to be marketed in the United States. And we made progress on the twenty-one significant R&D

programs that are currently funded, including Savanna reagents, instrument and test cartridges.

Moving forward, as I said earlier, 2019 is expected to be another highly productive year for us on many fronts. In addition to selling our current products, our global commercial teams will have new products to commercialize. The European team will be spending time on a limited, targeted launch of TriageTrue Troponin I, as well as the Sofia Vitamin D and Lyme Disease assays. And in the US, the commercial organization will be focused on adding Sofia Lyme to the thousands of Sofia 2 CLIA waived sites starting this summer. Importantly, we will do all that leveraging the current infrastructure, as we did when we added the cardiovascular and toxicology portfolio, which continues to be a focus. In fact, as I mentioned earlier, 2018 revenues were $267 million. During the Q&A, Randy can take you through the puts and takes that created the lumpiness that we saw during the year, but at the end of the day, we think that we have a handle on the overall growth rate, regardless of when, and in which quarter our distribution partners order products. For 2019, we expect to grow those businesses year over year - in total -- by 4%.

In terms of near-term product development in 2019, we expect to initiate clinical trials for Sofia 2 Strep 98 and for Sofia 2 C. difficile in a month or so, both of which we plan to commercialize in early 2020, if not sooner, depending on the timing of FDA clearance. Regarding Savanna, our excitement increases as we move closer to product launch. There are always technical issues to resolve, but our confidence in our ability to launch an exceptional product is quite high. I've said before that we intend to have a flawless launch with four or more multiplexed assay cartridges FDA cleared and immediately available to our customers; therefore, the timing of our launch is highly dependent on us conducting multiple clinical trials simultaneously, CE Mark, and then review by the FDA of course. And just so everyone knows. I will trade off timing of launch - just to hit a date - for flawless execution and significant market impact with the initial global launches of Savanna. I think it's that important to us. Having said all that, not withstanding a major obstacle that I'm not aware of, I see nothing that would have a material impact, favorable or unfavorable, on the 2023 forecast that we presented at our analyst day last year.

Switching gears, it's February, and in fact the same Valentine's day week of the month in the last two years when Influenza peaked before

declining. So, it's probably a good time to talk about flu this quarter. Using data in our Virena database and looking at the period ending Friday, February 8, we see a very slight reduction in positivity rates for a handful of states and a slight hint that influenza B may be starting to come up. There is still a lot of influenza A in the United States, however, and I believe we can expect the positivity rates to remain high for a few more weeks; therefore, people presenting with ILI should continue to be tested, and we should expect little reduction in test rates. Positivity rates for those patients tested in most states are at 25% to 35%, which is still very high. In terms of volumes of tests, it's important to look at the states with larger populations with greater propensity to test. California and Florida positivity rates and volumes have been high for several weeks now, and Texas is still climbing. New York and North Carolina are still quite high. There are some states with positivity rate above 40%, but those are lower volume states. Another way to assess the magnitude of the season is to look graphically at out-sales by week from Distribution to our customers over that last few seasons. Despite an apparent slower ramp up this season versus last year, the last four weeks have shown an acceleration that is unprecedented. At this point, the range of testing that we had suggested for this quarter, which was a reduction from last year's Q1, seems appropriate, and we are sticking with our internal projection for influenza testing revenue.

Finally, before closing, I'll comment briefly on the Beckman matter. With respect to the ongoing Beckman litigation, on January 18, 2019 we filed our petition for writ of mandate with the Court of Appeal, seeking immediate appellate review of the Court's December 7, 2018 ruling. Whether the Court of Appeal will review the merits of the writ petition is discretionary, and it is common for the Court of Appeal to require the parties to complete the underlying trial court litigation before appellate review. While we believe that our writ is well founded and should be granted now, we acknowledge that on most occasions courts of appeal prefer to hear all matters after the end of the entire case.

On February 7, 2019, the trial Court stayed the remaining litigation on Beckman's second cause of action pending a decision from the Court of Appeal on whether it will hear the merits of Quidel's writ petition. The trial Court also vacated all deadlines in the matter, including the trial date. Once the Court of Appeal issues its decision on whether to review the merits of Quidel's writ petition, the parties are to report back to the trial Court. We expect that to occur in the March/April timeframe. And once again, we remain extremely confident that at the end of this process that we will prevail, and our agreements with Beckman will remain in effect.

In conclusion, what a quarter, what a year, and what a company. 2018 was truly a year for the ages, a year not possible without the unbelievable talent and can-do attitude that we have across all functions. And importantly, a year that positions us for solid growth over the next several years. We're excited, we're productive, and we're happy.

Randy....?

RANDY STEWARD

Fourth Quarter Financial Results

Thank you, Doug. Good afternoon everyone. As we reported earlier today, total revenues for the fourth quarter of 2018 were $132.6 million dollars, as compared to $114.9 million dollars in the fourth quarter of 2017. The 15 percent increase was primarily due to a 34% increase in Cardiac Immunoassay revenue, 30% growth in Molecular Diagnostic Solutions, and 3% growth in Rapid Immunoassay. These increases were slightly offset by a 6% decline in our Specialized Diagnostic Solutions.

Cardiac Immunoassay revenue was $62.9 million dollars, a growth of 34% in the fourth quarter of 2018. Revenue growth for Cardiac was

mostly due to the incremental revenue in China as we returned to more consistent ordering patterns from our customers. Also, in Q4 2017, we minimized shipments to China in order to reduce the amount of inventory at distribution. The total year over year Cardiac revenue improvement in China was approximately $14 million dollars. Of the $62.9 million dollars in Cardiac revenue, the split was $35.9 million dollars for the Triage business, and $27.0 million dollars for the Beckman BNP business.

First, let's talk about Triage. From a geographical perspective, Triage revenue grew approximately $8 million dollars in China from the fourth quarter of the prior year, due to more normalized ordering patterns. The U.S. grew 17% from the fourth quarter of the prior year, and Europe was down 5%.

With regard to the $27.0 million-dollar Beckman BNP business, this product category grew 28%, or $6.0 million dollars as compared to last year, again driven by China. In the quarter, both the U.S. and EMEA were down 1%.

For the year, Cardiac Immunoassay revenue grew to $266.5 million dollars. Included in this amount, total Triage business revenue was $147.6 million dollars, and the geographic split for Triage revenue was $65.5 million dollars in the U.S., $33.6 million dollars in China, and EMEA was $24.1 million dollars. The Beckman BNP business was $119.0 million dollars for the year, consisting of $72.3 million dollars in the U.S., $21.3 million dollars in EMEA, and $20.7 million dollars in China. The Cardiac Immunoassay category is going to experience some lumpiness in revenues from quarter to quarter due to logistical and geographical factors, as well as timing and shipment of orders by distribution based on inventory levels. The big picture is that there is solid demand for our products, and we are optimistic about our ability to grow the business. As Doug has stated previously, in 2019, we expect to grow the Cardiac Immunoassay business by about 4%, to reach approximately $277 million dollars for the year.

Rapid Immunoassay product revenues increased 3 percent to $50.4 million dollars in the fourth quarter of 2018 as compared to $49.1 million dollars in the previous year. Within this category, Sofia products grew 17 percent from the fourth quarter of 2017 to $33.9 million dollars, while QuickVue product revenues declined 19% to $15.4 million dollars.

Total Influenza revenue, which includes rapid immunoassay, DHI respiratory and molecular diagnostics, grew 4% in the quarter to $34.9 million dollars. The Influenza rapid immunoassay revenue split was $26.3 million dollars from Sofia versus $4.9 million dollars from QuickVue. Total Strep revenue was up 2% and RSV was up 20%.

Revenue in the Specialized Diagnostic Solutions category decreased 6 percent in the fourth quarter to $13.4 million dollars, driven by a 5% decrease in our DHI revenues.

Our Molecular Diagnostic Solutions category increased 30 percent in the quarter to $5.8 million dollars due to a 71% growth in Solana. We continue to see strong growth with our Solana platform, specifically with the Strep A assay. We believe that we will continue to realize increasing demand for the Solana platform. We expect to grow molecular revenue by a minimum 20% in 2019, driven by incremental Solana instrument placements and increased assay utilization.

Gross Profit in the fourth quarter of 2018 increased $23.0 million dollars to $82.1 million dollars. The dollar growth was due to increased sales volumes and improved product mix from Cardiac Immunoassay and

Sofia products. Gross profit margin in the fourth quarter of 2018 was approximately 62 percent, as compared to 51 percent in the fourth quarter of 2017. Excluding acquisition-related costs, inventory step-up amortization, and amortization of intangibles, the legacy Quidel business gross margin was 69%, the Triage gross margin was 52%, and the BC BNP Business gross margin was 63%. For the full year, we achieved the upper end of our full year guidance, achieving a GAAP gross margin of 60% - a very solid performance.

R&D expense increased by $2.0 million dollars in the fourth quarter as compared to the same period last year. This increase is due to investments made toward our Savanna project. We expect that our R&D expense in 2019 should be similar to last year, between the range of $50 million to $55 million dollars as we continue to invest in Sofia menu expansion and Savanna.

Sales and Marketing expense in the fourth quarter of 2018 was in line with the fourth quarter of 2017. For the full year 2019, we expect Sales and Marketing expense as a percentage of revenue to be between 50-100 bps less than last year.

G&A expense increased by $3.6 million dollars in the quarter, primarily due to incremental costs associated with the globalization of our infrastructure. We expect G&A expenses to be between $48-$50 million dollars for the full year 2019 as we complete the globalization of our infrastructure.

In the fourth quarter, interest expense was $4.5 million dollars, a significant reduction from Q4 of 2017. In the year, we reduced our senior credit and revolving credit facility by $201.8 million dollars, and our convertible debt by $108.8 million dollars, as well as made the first $48 million-dollar payment to Abbott on the BNP deferred and contingent consideration.

In the quarter, we recorded an income tax benefit of $9.7 million dollars, mostly the result of reversing our tax valuation allowance. For the full year, we start with the enactment of the Tax Cuts and Jobs Act, the U.S. Federal Corporate Tax Rate was reduced from 35% to 21% effective January 1, 2018. In the year, the Company released $13.4 million dollars of its valuation allowance against its net deferred tax asset balance, since it is more likely than not that a portion of these deferred tax assets will be utilized in the future before they expire. Additionally, this overall tax provision includes beneficial impacts of $9.3 million

dollars from equity compensation gains to employees that occurred during the year and $3.6 million dollars from the generation of Federal and state research credits. The significant drivers of year over year differences in the income tax provision are the increased profitability, offset by the change in the corporate tax rate, increased stock-based compensation activity and the impact from the reversal of the valuation allowance.

Net income for the fourth quarter of 2018 was $32.5 million dollars, or $82 cents per diluted share, as compared to net loss of $5.1 million dollars, or $(0.15) cents per share, for the fourth quarter of 2017. For the full year, we achieved net income of $74.2 million, GAAP EPS of $1.86, and non-GAAP EPS of $3.04, a very rewarding year.

As Doug communicated previously, our capital deployment strategy in 2018 was to aggressively de-lever the business, with the goal of reducing our leverage ratio from 4X to 1.5X by year-end. As stated previously, we accelerated our debt reduction initiatives in 2018. The result is that we exceeded our internal target, and are now under 1X leverage. As of today, we have paid down an additional $20 million dollars on our revolving credit facility and have an outstanding

Revolving Credit Facility obligation of $33 million dollars, with a borrowing capacity of approximately $142 million dollars. From a balance sheet perspective, our company is very strong and well positioned for M&A, licensing or other partnership opportunities in support of our longer-term growth objectives.

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 a great year, and we're in terrific shape to achieve our growth objectives over the next few years. We know what to do from here, and we have the right people to get the job done. Thanks again for being on the call.

OPERATOR

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