QUIDEL FOURTH QUARTER 2020
CONFERENCE CALL SCRIPT
Thursday, February 18, 2021
2:00 p.m. PT/ 5:00 p.m. ET

OPERATOR:

Ladies and gentlemen, thank you for standing by.

Welcome to the Quidel Corporation Fourth Quarter and Full Year 2020 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 fiscal fourth quarter and full year 2020 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 18th, for a period of 24 hours.

Please note that this conference call will include forward-looking statements within the meaning of Federal securities laws. Forward-looking statements by their nature involve material risks, assumptions and uncertainties. In particular, our expectations and assumptions around the impact of the COVID-19 pandemic on our business, results of operations and financial condition and that of our suppliers, customers and other business partners are uncertain and subject to change. Many possible events or factors could affect our future financial results and performance, such that our actual results and performance may differ materially from those in the forward-looking statements. For a discussion of such factors, please review Quidel's

most recent annual report on Form 10-K, including the section titled “Risk factors”, 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 18, 2021. 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 and twelve months ended December 31, 2020. 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 take your questions.

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

DOUG BRYANT

Good afternoon everyone. Thanks for joining us. Given the many factors that are affecting our business, I will be brief so that we can address as many of your questions as we can during the hour.
You've seen the numbers for the quarter, both revenue and margin, which speak for themselves. We had a very good quarter, some might even say excellent. Here are a few comments that may provide a bit more color.

First, our Virena deidentified testing data that are collected in real time from a large and statistically significant set of the same Sofia 2 analyzers reflected what we were all hearing in the news in terms of prevalence of COVID in the U.S. July and August testing volumes in the professional, non-reference lab, non-government segments were stable, then they jumped sequentially in September and October, then peaked in November. December's testing volume was slightly higher than October, and January was slightly above September. In other words, when graphed, the Virena testing data for the period from September through January are an almost perfectly symmetrical bell-shaped curve. As a result, shipments of Sofia SARS Ag into distribution and out-sales from distribution into hospitals, urgent care centers and other professional use settings spiked in the fourth quarter and were large. We kitted and shipped every Sofia SARS Antigen and combo test that

we manufactured; and, importantly we exited the year with unfilled orders.

Second, while we gained clearance from the FDA to market Solana SARS and QuickVue SARS Antigen under an EUA, which is an accomplishment, approvals for both products came later than we had expected, and revenue for these products was well under what we had forecasted internally. We manufactured and pouched several million QuickVue SARS Antigen tests but given constraints on kit components did not kit them, as we chose to fill Sofia orders instead.

Third, at the request of many very large customers, and informed by experts in the epidemiology community of the potential for a perfect storm of influenza and COVID during the traditional respiratory season and the impact on an already burdened healthcare system, we built and shipped millions of Sofia SARS and flu combination assays, tests that were priced higher than the Sofia SARS-only tests. This resulted in increased revenue and margin for the quarter, but not as much as we had initially forecasted internally. As it became clear that ILI percentages were low, relative to previous years, we began to reduce the volume of combo manufactured to SARS-only. For the quarter, the unit volume was approximately 37% combo and 63% SARS-only.

During the fourth quarter, the R&D and Regulatory teams performed extremely well. With the Solana and QuickVue EUA clearances, our fifth and sixth, our Quidel scientists became the most prolific COVID diagnostic assay developers in our industry. We made progress on our submissions for QuickVue SARS Antigen for both prescription use and OTC claims. We expect to submit our Sofia fingerstick POC serology assay before the end of this quarter, and have begun a major vaccine study in which we are tracking semi-quantitative N, S1 and S2 responses over time from subjects that have received COVID 19 vaccines. Sofia Q remains on track. We validated our manufacturing processes for the instrument and will move to mass production this quarter, which will enable us to deliver as many as 100,000 instruments by the end of May. Savanna, our rapid POC PCR instrument remains on track as well. In fact, we began clinical trials in the U.S. for our RVP4 assay and the instrument on Tuesday of this week. And finally, we made steady progress with the Triage True, High Sensitivity Troponin assay, with the number of clinical sites that are ready to enroll patients increasing every week. Overall, a great quarter for the R&D teams across the organization.

During the quarter our manufacturing and supply chain teams made great progress. Line 7 is up and running and we can manufacture the Sofia cartridges that we had expected. The number of tests we can kit each week has lagged our ability to make cartridges and depends on the availability of each of the kit components. The variability in the number of kits shipped has narrowed, however, as we made progress in securing our supply chains. Overall, a great quarter for the Operations group.

In summary, 2020 was a fantastic year for our company, and Q4 was phenomenal. I could not be prouder of the entire organization for their resilience, and for having risen to the challenge of the COVID pandemic. Quidel was built for this sort of response, but we still had to execute – and execute we did.

And now it's 2021, and we still have lots of work to do. I recognize that our investors would really like to be able to peg our performance for the year and for each quarter. As much as I would like to be helpful, I'm not sure that we can provide anything further that would be precise enough to be helpful in your modeling. But perhaps a listing of what's known and unknown might be helpful. Let's start with what we know.

There was a testing spike tied to increased COVID prevalence that peaked in November. Orders for our Sofia SARS product were placed, and distributors reacted by stocking up. After the spike, testing in the professional segments resumed to where they were previously, concomitant to the reduction in COVID prevalence, to a level of demand that we were previously struggling to fulfill. For the first time, we have modest inventory, but have significant interest from what we call New Markets, which include many categories like travel, entertainment, sports and dining. From our Sofia launch in May through the fourth quarter we have been unable to begin to consider any of those opportunities. We now have a decision to make regarding whether we can support some of these new market opportunities – or not, given our commitments to our current customers.

We placed a significant number of Sofia instruments in the year and continue to ship at a high rate. Each of the Sofia professional placements is on a multi-year contract with a claw-back provision. A high percentage of the new placements are new Quidel customers; further, the new agreements very often include influenza, Strep A and RSV, which bodes well for us in the future.

It has been very cold across most of the country. But no influenza of significance, and no recurring price lift due to sales of Sofia ABC Combo. There is some inventory of Sofia SARS and Flu combo product at distribution and with customers. The dating of our products is long, however, dramatically better than our competitors, which interestingly makes us a better value relative to lower price competitors. Very little Sofia SARS product, only about 5%, has been shipped to federal or state stockpiling programs; therefore, our products have not really been stockpiled in a meaningful way.

And here's what we don't know.
How long will it stay cold, and what impact is the weather having on prevalence and demand for testing, and what orders will our distribution partners place each quarter, which is often driven by leading indicators like upticks in prevalence.

How much longer will molecular companies and labs be able to rely on better sensitivity of PCR to delay the avalanche of rapid testing that the federal government is suggesting the country needs to get the economy back on track.

Whether the demand for COVID tests in new market segments, to include OTC, is as significant and sustainable as some are projecting. Or what pricing and margin will look like as the capacities of the larger manufacturers in our industry increase.

How good we are, really. Will we continue to execute at a high level in R&D and operations, and commercially, such that we continue to maintain a leadership position in the COVID-19 testing market?

Clearly there is a lot to think about, and many variables that may make Quidel's business unforecastable at any level of precision, although we will try to be helpful.

And finally a comment about M&A. The short answer is yes. Yes, we continue to look at just about everything out there, most of which isn't a good fit for us, and we move on. But you should leave that to us to figure out, and in return I promise that we will not do anything stupid. We have a fantastic company and highly profitable business. We have cash and easy access to capital but are not compelled to acquire anything that isn't a great fit strategically. Bold claims by new competitors can be fun. And rumors can sometimes be fun, too. But sometimes they can be annoying – and time consuming.

And on that very positive note, let me say again, we had a terrific year, and add that I think we are poised for another two or three great years in our future. Prior to 2020, and to the COVID-19 pandemic, Quidel was already performing well, executing a strategy that we believed in and are firmly committed to. Our strategic intent to leverage immunoassay and molecular technologies to bring testing closer to the patient — to democratize testing — remains unchanged. Our ability to address the testing challenge presented by this pandemic will allow us to invest in the manufacturing capacity we will need in the future. In effect, the COVID pandemic has given us the opportunity and the funds to accelerate, and in a way to de-risk the execution of our strategy.

Randy?

RANDY STEWARD

Fourth Quarter Financial Results

Thank you, Doug. Good afternoon everyone. The year 2020 was of significant importance to Quidel, and we could not have realized such substantial strides without Doug's steady leadership. I am truly impressed at the level of passion and dedication shown by our employees, and we are making a profound difference in people's lives

and livelihoods. We had a great year in the midst of a challenging time, and we believe that the company is well positioned for a strong 2021.

As reported, total revenues for the fourth quarter of 2020 were $809.2 million dollars, as compared to $152.2 million dollars in the fourth quarter of 2019. Foreign currency had a positive impact of $1.4 million dollars in the quarter, and had a minimal impact on the growth rate. The 432% revenue growth was due to the considerable demand for our COVID-19 diagnostic products. Total COVID-19 revenue was $678.7 million, of which $591.2 million was from our Rapid Immunoassay products, and $87.6 million was from our Molecular products.

Within our product categories, Rapid Immunoassay revenues increased $566.3 million dollars to $631.3 million dollars in the fourth quarter of 2020, driven by demand for rapid antigen Coronavirus products. Within this category, Sofia products grew $573.8 million to $620.4 million dollars, of which $587.6 million dollars was attributed to Sofia SARS Antigen and Sofia Combo ABC product sales. The revenue mix was 46% Combo ABC and 54% antigen. QuickVue product revenues were $9.8 million dollars, of which $3.6 million dollars were for the SARS Antigen product. In the fourth quarter, we did not realize the typical ramp-up of distributor purchases of Influenza, Strep, and RSV as in

previous years, as we intentionally prioritized our production and shipments toward the SARS antigen tests. As a result, Influenza Rapid Immunoassay revenue was $28.1 million dollars, with approximately 90% of that revenue derived from the Sofia platform. This compares to $45.0 million dollars in Influenza revenue for the same period last year.

For the Cardiometabolic Immunoassay business, revenue was $70.0 million dollars, a 6% increase versus the fourth quarter of 2019, and up 8% sequentially. Of the $70.0 million dollars in Cardiometabolic revenue, $36.4 million dollars were derived from the Triage business, an 8% increase from Q4 of 2019; and $33.6 million dollars from the Beckman BNP business, a 4% increase over Q4 of 2019. For Triage, growth came from all geographic areas except for China, which showed a slight decline. This trend was realized with the Beckman BNP business, as well. Overall, growth in our Cardiometabolic category was broad-based, which is a very good sign for the category going forward.

Revenue in the Specialized Diagnostic Solutions category decreased 20% in the fourth quarter to $11.5 million dollars, mostly driven by a decline in our respiratory products from our cell culture business.

Our Molecular Diagnostic Solutions category increased $89.4 million dollars in the quarter to $96.4 million dollars, driven by $87.6 million dollars in sales of our COVID-19 products. Solana COVID-19 revenue was approximately $400,000 dollars in the quarter, less than our internal estimates, due to a later-than-anticipated EUA approval for the product - which was December 23rd - and this impacted the launch. We continue to see good growth from these products, as more small and mid-sized labs look to bring molecular testing in-house.

In the quarter, total Influenza revenue, which includes Rapid Immunoassay, DHI Respiratory and Molecular Diagnostics, decreased by 36% to $32.3 million dollars. The decline was due to a very low prevalence of Influenza in the fourth quarter, as well as the introduction of our Sofia Combo ABC test, which is not included in the Influenza revenue number.

Gross Profit in the fourth quarter of 2020 increased $606.7 million dollars to $701.5 million dollars, and gross profit margin was 87%. The significant increase was a result of the introduction of high-margin Coronavirus products as well as running significantly more volume through our manufacturing plants with relatively fixed overhead.

We continue to invest heavily in R&D, with the goal of launching additional COVID-19 diagnostic assays, advancing on our Savanna initiatives, as well as introducing new Sofia assays and next generation platforms, such as Sofia Q, formerly known as Project Sniffles. From a Sales and Marketing perspective, we will continue to invest in people and resources to include expanded Customer Service Support, as we expand our customer reach and enter new markets, such as at-home testing and occupational health.

In the quarter, we retired $6.8 million dollars in principal of our Convertible Notes. We have now retired all the principal outstanding amounts on our Convertible Notes. The only remaining debt obligations we have on our Balance Sheet are a small facility lease obligation and the deferred and Contingent Consideration, which currently has a remaining principal amount of $136 million dollars.

As it relates to the annual provision for income taxes, we recorded $230.0 million in income tax expense, and the effective tax rate was 22%. State tax obligations increased our rate above the federal statutory rate of 21%. This was partially offset by the tax benefits from excess stock-based compensation. For fiscal year 2021, we are currently estimating a full year effective tax rate between 22% - 23%,

excluding any potential impact of legislation, which remains uncertain. The upper end of this range is higher than previous estimates due to the increase in pre-tax income expected and the proportional impact of other rate impacting items to this increased pre-tax income.

Regarding our contract with the NIH, we are progressing nicely in achieving our manufacturing capacity goals. We have achieved four of the seven milestones and have received $26 million of the up to $70 million dollar contract value.

As of this week, we have a cash and cash equivalent balance of approximately $760.0 million dollars. As we mentioned previously, we have no outstanding indebtedness except for the lease obligation and the Contingent and Deferred Consideration. In 2021, we are expecting to spend approximately $300.0 million in capital expenditures, the majority of which relates to plant capacity expansion. In all, we have a very strong capital structure, access to credit, and excellent cash flow, which places us in a great position to support our future initiatives such as increasing our R&D investment, strengthening and expanding our supply chain, aggressively ramping up our manufacturing capacity, and pursuing strategic M&A.

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 an excellent fourth quarter, we're well positioned for this year, and we're in good shape to achieve our growth objectives over the next few years. 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.