

QIAGEN

Q2/2019

CONFERENCE CALL

TRANSCRIPT

July 31, 2019



QIAGEN Q2/ 2019 CONFERENCE CALL TRANSCRIPT

JOHN GILARDI: Thank you, and welcome to our conference call.

The speakers today are Peer Schatz, the Chief Executive Officer of QIAGEN, and Roland Sackers, the Chief Financial Officer. Also joining us is Phoebe Loh from our IR team.

Please note that this call is being webcast live and will be archived on the Investors section of our website at www.qiagen.com. A copy of the press release is also available in the same section.

(SLIDE 2: FORWARD LOOKING STATEMENTS)

JOHN GILARDI: Before we begin, let me cover our Safe Harbor statement. The discussion and responses to your questions on this call reflect management's view as of today, Wednesday, July 31, 2019.

We will be making statements and providing responses to your questions that state our intentions, beliefs, expectations or predictions of the future. These constitute forward-looking statements for the purpose of the Safe Harbor provisions. These statements involve risks and uncertainties that could cause actual results to differ materially from those projected. QIAGEN disclaims any intention or obligation to revise any forward-looking statements. For more information, please refer to our filings with the U.S. Securities and Exchange Commission.

We will also be referring to certain financial measures not prepared in accordance with generally accepted accounting principles. You can find a reconciliation of these figures to GAAP in the press release and the presentation for this call.

And as a last point, I wanted to provide some context as to why we made the pre-announcement on July 24. This was due to the requirements of German securities law, and the ad-hoc system that requires companies to make a public disclosure once there is a material news development. The material news was the change in our China partnership for GeneReader and we thought it would be helpful for analysts and investors to see this information also together with the financial update and outlook.

I will now turn the call over to Peer.

(SLIDE 4: Q2/H1 2019 OVERVIEW – PEER)

PEER SCHATZ: Thank you, John, and thank you to all of you for joining us for this call.

I have the following key messages for you today:

First, we achieved our outlook for net sales growth and adjusted earnings per share. Net sales were 381.6 million dollars, and rose 5% at constant exchange rates. Adjusted earnings per share were 34 cents at CER, and 33 cents on a reported basis.

Second, we shared some important updates while we continue advancing our Sample to Insight portfolio.

We announced on July 24 our decision to restructure the current format of our clinical sequencing joint venture in China, which has an impact on our outlook for 2019. The joint venture had been formed and announced in the middle of 2017.

After a review period and discussions with our partner, we believe this decision is the best solution. A key factor was the slower-than-expected progress in bringing in-vitro diagnostic clinical sequencing to customers in this country.

We had been anticipating about 30 million dollars of sales from this joint venture in 2019, and for about 20 million dollars in the second half of this year. These involve primarily revenues for the services provided by QIAGEN to develop in-vitro diagnostic assays on behalf of the joint venture, as well as the sale of the GeneReader NGS System in China and other consumables and products to the joint venture at transfer prices.

At the same time, it is important to note that our universal NGS portfolio in this country is not run through the JV, but has always been commercialized directly by QIAGEN. These universal NGS products are independent from GeneReader and have been performing very well in China, and also on a global basis.

So we continue to believe in the promise of NGS technologies in China and we will now consider various new options to participate in further growth opportunities.

Moving to the QuantiFERON-TB test, sales as expected were below the usual growth trajectory of at least 15% CER growth and rose 6% CER in the second quarter of 2019. This was in line with our outlook for mid-single-digit CER growth.

This more moderate growth was due to the comparison against the year-ago period which marked the end of the inventory building during the conversion of customers from the third generation to the fourth generation QuantiFERON assay. We continue to expect full-year 2019 growth above our 15% CER target.

We also had our second important FDA approval this year for a new and novel therascreen companion diagnostic assay, and this assay tests for variants on the PIK3CA gene to help guide the use of a new Novartis therapy for breast cancer.

This announcement was in addition to our previously announced approval in April for the therascreen FGFR companion diagnostic assay to help guide the use of a new Janssen therapy for urothelial cancer.

We are in a period with multiple new product launches. These include the QIAstat-Dx system for syndromic testing that received FDA approval in May and is now available in the U.S., Europe, and many other countries, as well as the integrated PCR system NeuMoDx that we are distributing in Europe. We have six CE-IVD assays on NeuMoDx in Europe, and have a goal to offer 11 assays by the end of 2019.

For our Life Sciences customers, we are seeing good progress on the rollout of the new QIAcube Connect sample processing instrument, which replaces the first generation that had over 8,000 placements. The development of the new digital PCR system for 2020 launch is also progressing well.

Third, as you saw in the press release on July 24, we have updated our full-year 2019 outlook.

We now expect net sales growth of about 5 to 6% CER for the year and for adjusted EPS of about 1.42 to 1.44 dollars per share, also at CER.

We are committed to maximizing the opportunities for our exciting new product launches and allocating resources to the best opportunities.

So as a quick summary, we achieved our outlook for the second quarter of 2019, and have made an important decision on how to address NGS growth opportunities in China.

QIAGEN is positioned for an improving growth profile in the coming years as we strengthen our portfolio and set our sights on the new mid-term targets we announced in June for an 8 to 9% CER sales compound annual growth rate from 2019 to 2023 and for at least a 10% CER CAGR for adjusted earnings during the same period.

I would now like to hand over to Roland.

(SLIDE 5: Q2/H1 2019 FINANCIAL REVIEW – ROLAND)

ROLAND SACKERS: Thank you, Peer.

Good afternoon to those of you in Europe and good morning to those of you in the U.S. I will first review the financial results for the second quarter and later provide an update on the outlook.

Net sales in the second quarter of 2019 were 381.6 million dollars, and rose 5% at constant exchange rates and in line with our outlook for 5% CER growth. Sales growth on a reported basis was 1%, and this was due the significant adverse currency headwinds that were in line with our outlook for the period. The acquisition of N-of-One, which was completed in January 2019, contributed very modest sales for the period.

For the first six months of 2019, net sales were 730.3 million dollars, and also rose 5% CER and were up 1% on a reported basis due to four percentage points of headwinds. About one percentage point of sales growth came from the launch of QIAstat-Dx, which was acquired in April 2018, while the rest of the portfolio provided a solid four percentage points of growth.

These results also absorbed a combined one percentage point of headwinds from the ongoing decline in revenues from third-party instrument service contracts and the divestment of the veterinary assay portfolio that we did in 2018.

Moving down the income statement, the adjusted gross margin was 70.8% of sales in the second quarter of 2019 compared to 71.5% in the year-ago quarter. For the first half of 2019, the adjusted gross margin also declined slightly to 70.3% of sales from 70.8% in the same period of 2018.

Adjusted operating income declined 2% to 99.1 million dollars from 101.1 million dollars in the second quarter of 2018, absorbing the investments for the development, production ramp-up and commercialization of new instruments. The adjusted operating income margin was 26.0% compared to 26.8% in the prior-year period.

These trends remained relatively consistent from the first quarter of the year, with adjusted operating income down 1% to 177 million dollars compared to 178 million in the first half of 2018.

As a result, the adjusted operating income margin was 24.2% compared to 24.7% in the first half of 2018.

In terms of adjusted earnings per share, we were at the high end of our outlook for 34 cents CER. Given the currency headwinds, adjusted EPS on a reported basis was 33 cents. The adjusted tax rate was 20% for the second quarter, which was in line with the outlook for the quarter. For the first half of 2019, adjusted EPS was 62 cents CER, and the adjusted tax rate was also 20%.

(SLIDE 6: Q2/H1 2019: CUSTOMER CLASSES – ROLAND)

ROLAND SACKERS: I would like to now review our sales results based on the product categories and to our customers in the Life Sciences and Molecular Diagnostics.

Among the product categories, consumables and related revenues rose 4% CER to 335 million dollars in the second quarter of 2019 and represented 88% of total sales. For the first half of 2019, consumables and related revenues rose at the same 5% CER pace, reaching 648 million dollars and represented 89% of sales.

Instrument sales rose at a much faster rate in the second quarter of 2019, growing 9% CER to 47 million dollars and representing 12% of total sales. Key drivers were the rollout of the new QI-Acube Connect instrument for sample processing to Life Sciences customers, as well as sales contributions from QIAstat-Dx and other instruments in Molecular Diagnostics.

As mentioned before, we have reduced our third-party instrument service contracts, which has created a sales headwind in recent quarters. Excluding service revenues, instrument sales were up 15% in the second quarter.

For the first six months of 2019, instrument sales rose 5% CER to 83 million dollars and represented 11% of total sales, and underlying sales were up 15% CER excluding third-party service revenues.

In the Molecular Diagnostics customer class, sales were up 5% CER to 188 million dollars in the second quarter of 2019, and represented 49% of total sales. This came from a combination of solid double-digit CER sales growth for instruments, even while absorbing the decline in instrument service revenues, and mid-single-digit CER growth in consumables and related revenues.

Sales of the QuantiFERON-TB test grew 6% CER, while companion diagnostic co-development revenues were under pressure and reduced growth in this customer class by two percentage points with the 21% CER decline to 11 million dollars. We had ongoing solid placements of the QIAsymphony system and double-digit CER growth in related consumables and also contributions from the launch of QIAstat-Dx in the U.S. along with sales in Europe. For the first half of 2019, Molecular Diagnostic sales rose 7% CER and were 49% of total sales.

In the Life Sciences customer class, sales were also up 5% CER, and reached 194 million dollars in the second quarter of 2019 that represented 51% of total sales. We experienced single-digit CER growth in both instrument sales, as well as consumables and related revenues compared to the second quarter of 2018. For the first half of 2019, Life Science sales grew 4% CER and represented 51% of total sales.

Within the Life Sciences, sales to Pharma customers rose 4% CER with growth contributions from both consumables and instruments during the second quarter. Sales in the Academia / Applied Testing customer class rose 5% CER, with continued double-digit CER growth in instrument sales, in particular due to the launch of QIAcube Connect earlier this year, and mid-single-digit CER growth in consumables.

(SLIDE 7: Q2/H1 2019: GEOGRAPHIC – ROLAND)

ROLAND SACKERS: I would like to now review the performance among our three geographic regions.

The Asia-Pacific Japan region led the performance with 12% CER growth in the second quarter of 2019 to 83 million dollars, providing 22% of total sales. We were pleased with double-digit CER growth in China which follows on from growth rates above 20% for the last two quarters. This is due to increased demand in the Life Sciences and solid trends for our QuantiFERON-TB test and other Molecular Diagnostic products, while sales in Japan were largely unchanged from the second quarter of 2018. For the first half of 2019, the Asia Pacific Japan region grew 10% CER to 151 million dollars and represented 21% of sales.

The Europe Middle East and Africa region grew 5% CER to 118 million dollars in the second quarter, and represented 31% of total sales. We saw soft trends in the core Western European countries – in particular France, Italy and the United Kingdom – but saw improving sales in Turkey, the Middle East and Africa. For the first half of 2019, sales grew 4% CER to 227 million dollars and represented 31% of total sales.

The Americas region grew only 1% CER to 181 million dollars in the second quarter, and represented 47% of sales, with the U.S. growing at this same rate as the region due mainly to the slower growth rate for QuantiFERON-TB. At the same time, we had improving trends in Brazil and Mexico at higher-single-digit CER rates. For the first six months of 2019, the Americas grew 4% CER to about 350 million dollars and represented 48% of total sales.

In terms of the top 7 emerging markets, these countries collectively grew 20% CER in the second quarter of 2019, and represented 18% of sales. The top performers were Turkey and China, while Korea was the only one to show a year-on-year decline against growth in India, Mexico, Brazil and Russia.

(SLIDE 8: Q2 2019: BALANCE SHEET / CF – ROLAND)

ROLAND SACKERS: I would like to now give you an update on our balance sheet and cash flow.

At the end of the first half of 2019, our leverage ratio stood at 1.7 times net debt to EBITDA and remains unchanged from the end of the first half of 2018. We saw a decline in group liquidity to 786 million dollars from 900 million dollars in the prior-year period. At the same time, net debt increased to 978 million dollars from 863 million dollars in same period of 2018. This reflects primarily the influx of cash flow from the business as well as proceeds from the issuance of 500 million dollars of new cash-settled convertible notes against the outflow of about 430 million dollars for repayment of the 2019 cash-settled convertible notes in the first quarter of this year, as well as investments in the business and about 74 million dollars for the share repurchase program.

In terms of cash flow, we saw a decline in operating cash flow to 127.2 million dollars in the first six months of 2019 compared to 166.2 million dollars for the same period in 2018.

Among the key factors were cash payments for derivatives transactions and higher tax payments in part to settle tax audits for prior years, which were accrued for in the past.

Investments in property, plant and equipment were also higher in the first six months of 2019 at 54.4 million dollars compared to 42.9 million dollars in the same period of 2018. This was mainly due to investments in building up our manufacturing capacity to support new product launches, in particular QIAstat-Dx. As a result, free cash flow was 72.9 million dollars for the first half of 2019 compared to 123.4 million dollars in the same period of 2018.

I would like to now hand back to Peer for a strategy update.

(SLIDE 9: SUMMARY ON SAMPLE TO INSIGHT – PEER)

PEER SCHATZ: Thank you Roland.

I am now on slide 9 to give you an overview of key developments in our Sample to Insight portfolio.

I would like to point out two highlights here before going into greater detail on some areas of this portfolio. First, our flagship QIASymphony platform continues to show strong placement rates and good growth in related consumables, and we are on track to reach our target for more than 2,500 cumulative placements at the end of 2019.

Additionally, we reached an important milestone in surpassing one million patient tests analyzed with QIAGEN Clinical Insight. This is a significant number. This proprietary informatics solution pulls information from over 40 clinical and scientific knowledge bases including many proprietary ones such as the vast and continually updating QIAGEN Knowledge Base and this is playing a key role for our customers in enabling and advancing the practice of precision medicine.

(SLIDE 10: NGS – PEER)

PEER SCHATZ: On slide 10, I would like to provide more details on our portfolio for next-generation sequencing.

As mentioned earlier, we have decided to restructure our clinical sequencing joint venture in China. Sales from this joint venture were planned to be approximately \$30 million CER for full-year 2019, and weighted to the second half of this year. These involve primarily revenues for the services provided by QIAGEN to develop in-vitro diagnostic assays on behalf of the joint venture, as well as the sale of the GeneReader NGS System and other consumables and products to the joint venture at transfer prices.

I want to note that sales of the larger NGS revenue component, the so called universal NGS solutions in China are handled directly by QIAGEN in this country, and QIAGEN is experiencing strong growth in this portfolio. We intend to review various options on how to further add from the growth opportunities for NGS technologies in China and how GeneReader can be expanded from its current base in China in a new structure.

We expect overall NGS-related sales of about 180 million dollars at constant exchange rates in 2019 compared to the prior target of over 190 million dollars. This now reflects the changes in China and compares to over 140 million dollars in 2018 and represents a growth rate of around 30%.

Just as a reminder: there are three main components to the calculation of the NGS-related sales: NGS consumables, including gene panels; instruments and consumables for the GeneReader NGS System; and the last involves revenues from NGS-related bioinformatics solutions.

Additionally, we expect a decline of approximately 20 million dollars to reflect in companion diagnostic and other assay co-development revenues. All of the adverse sales impact due to the change in China is recorded in the Molecular Diagnostics customer class.

As I mentioned earlier, our portfolio of universal NGS solutions continues to see strong uptake in all regions. Most recently, we launched the QIAseq Expanded Carrier Screening panel that provides identification of targets, genes and other regions of interest responsible for more than 200 disease indications.

This new product leverages QIAseq's Single Primer Extension technology and is integrated with our bioinformatics solutions.

This new panel further expands our existing universal NGS portfolio of more than 30 off-the-shelf preconfigured gene panels in addition to an unlimited number of panels available through our customization services.

(SLIDE 11: QUANTIFERON – PEER)

PEER SCHATZ: I would like to now provide an update on QuantiFERON-TB, and our plans to expand the franchise of assays developed with this proprietary technology.

As an update on our collaboration with DiaSorin, we now have more than 120 DiaSorin LIAISON customers in Europe that have embedded the QuantiFERON-TB Gold Plus TB assay onto their systems. This is a great number so soon after the launch – and promising considering the large installed base still in front of us. In terms of the U.S., we are waiting for FDA approval during the second half of the year.

Our number one priority is further driving the conversion from the old skin test to the modern gold standard with QuantiFERON. More than 70 million skin tests are done annually. We see current global penetration at only about 20%, with ample room for growth. An urgent and important driver is the recent announcement by the U.S. Centers for Disease Control, or CDC, that they are expecting a 3 to 10 month nationwide shortage of tuberculin antigens required for performing this skin test. We are seeing shortages in other countries as well, including Germany.

Building on the DiaSorin collaboration, and our intention to offer a series of QuantiFERON-based assays on the LIAISON systems from DiaSorin, we have entered into a new agreement to co-develop a QuantiFERON-based test for earlier detection of Lyme disease on the LIAISON platforms.

The QuantiFERON-Lyme test will allow a new testing framework by linking QuantiFERON technology with the DiaSorin serology assays, where DiaSorin has a leading position, with the aim to offer a new dimension of clinical value through much earlier detection to allow much earlier treatment. This addresses a significant unmet medical need.

The QuantiFERON-Lyme test is planned to be used in conjunction with the Borrelia IgG and IgM assays, creating a highly synergistic portfolio on LIAISON for customers. The CE-IVD launch for this assay, which is planned for a market estimated at 400 to 600 million dollars of annual testing, is planned for 2021, and later in the United States.

(SLIDE 12: PRECISION MEDICINE – PEER)

PEER SCHATZ: In the area of Precision Medicine, where companion diagnostic assays are used to guide treatment decisions, and primarily for cancer patients, we had a successful quarter with the FDA approval and launch of two new companion diagnostics.

After the approval in April 2019 of our first FGFR assay for use with a new therapy from Janssen called BALVERSA, which was approved for use in treating patients with urothelial cancer, we received approval in June for the theascreen PIK3CA RGQ PCR Kit, which is also the first approval of this biomarker. It was approved by the FDA for use in identifying breast cancer patients suitable for treatment with the newly approved Novartis therapy PIQRAY, and was given approval for use with both liquid biopsy and tissue samples.

In fact, this is first companion diagnostic approved by the FDA for use in guiding treatment decisions in breast cancer using tissue or liquid biopsy specimens. This assay is expected to be used widely since it detects 11 PIK3CA-related mutations that are estimated to be present in approximately 40% of hormone receptor-positive advanced or metastatic breast cancer patients.

Both assays were offered in the U.S. through our Day-One Lab Readiness program, which enables LabCorp, NeoGenomics and Quest and others to almost immediately start offering these assays to physicians and patients following the approval of new targeted therapies.

In addition, we recently announced a new partnership with Inovio Pharmaceuticals to co-develop a companion diagnostic to guide the use of Inovio's DNA-based immunotherapy in late-stage development for the treatment of cervical dysplasia caused by the human papillomavirus, or HPV. Inovio's VGX-3100 has the potential to become the first FDA-approved treatment for HPV infection of the cervix and the first non-surgical treatment for precancerous cervical lesions associated with this virus.

(SLIDE 13: QIASTAT-DX and NeuMoDx – PEER)

PEER SCHATZ: I would like to update you on our newest Automation Systems – QIAstat-Dx and NeuMoDx.

QIAstat-Dx is our next-generation integrated, real-time PCR based platform for syndromic testing applications, and it was first launched in Europe in April 2018 with the respiratory and gastrointestinal panels.

In May, we received FDA clearance of the system along with the respiratory panel, and quickly began commercialization to gain as many placements ahead of the upcoming cold and flu season.

As part of the U.S. commercialization, we announced ahead of our recent Investor and Analyst Day in June that we have partnered with McKesson, one of the largest U.S. healthcare distribution companies, for them to serve as the exclusive distributor of QIAstat-Dx in the acute market segment of U.S. hospitals with 200 beds or less – an area where QIAGEN is not present with its commercial activities. McKesson also can become a non-exclusive distributor in the future for planned expansion of QIAstat-Dx into the non-acute retail clinics that are increasingly being found in U.S. retail pharmacies.

And for NeuMoDx, we are expanding the early installed base aggressively with placements in Europe and other markets outside of the U.S. for the 96 and 288 versions of this fully integrated next-generation molecular testing system.

We are now able to offer a menu with six CE-IVD cleared assays and are on track to offer 11 assays by the end of this year, in addition to the ability to allow customers to run LDTs in full random access. The two most recent CE-marked NeuMoDx assays in Europe involve detection of the cytomegalovirus and Epstein-Barr virus.

Future menu expansion plans include blood-borne viruses, women's health and transplantation assays. Rapid menu expansion is a key focus in our plans to capture growth opportunities in this large market opportunity estimated at around 3 billion dollars for low-plex testing, and high volume in hospital and reference lab networks.

With this, I would like to hand back to Roland.

(SLIDE 14: Q3 and FY 2019 OUTLOOK – ROLAND)

ROLAND SACKERS: Thank you, Peer.

I would like to now review our outlook for 2019.

As noted earlier, we have updated our outlook for total net sales growth of approximately 5 to 6% CER, reflecting the lower sales growth due to the restructuring of the clinical sequencing NGS joint venture in China. We have updated our outlook for adjusted diluted EPS to 1.42 to 1.44 dollars per share, also at CER.

As for currencies, based on rates as of July 29, 2019, in terms of net sales we expect a currency headwind of about 3 percentage points on results at actual rates. For adjusted EPS for the full year, we expect a currency headwind of about 3 to 4 cents per share.

For the third quarter, our outlook is for total net sales growth of about 4 to 5% CER, and this includes the adverse impact of the changes in China, but also for QuantiFERON-TB to grow above our full-year target for at least 15% CER growth.

Adjusted diluted EPS is expected to be about 35 to 36 cents per share, and at constant exchange rates.

In terms of currency impact for the third quarter, based on rates as of July 29, 2019, we expect headwinds of about 2 percentage points on net sales growth and about 1 cent on adjusted EPS.

With that, I would like to hand back to Peer.

(SLIDE 15: SUMMARY - PEER)

PEER SCHATZ: Thank you, Roland.

Here is a quick summary before we move into Q&A. Let me review what we have announced:

- First, we achieved our outlook for net sales growth and adjusted EPS in the second quarter of 2019.
- Second, we are focused on advancing our Sample to Insight portfolio and have had some important developments. We announced a change in our clinical sequencing strategy for China, and intend to review ways to capture growth opportunities in this important market. In other areas of our portfolio, we are moving ahead, especially with the QuantiFERON latent TB test, our expanding portfolio of automation systems and renewed focus on growth in the Life Sciences.

We are in a heavy lift phase with new product launches that are set to help accelerate our performance in the coming years, and are very proactively reallocating resources to support the most attractive opportunities.

- Third, we have updated our full-year 2019 outlook after the decision on the China joint venture.
- And fourth, we are determined to execute on our strategy to maximize the value of our portfolio with a disciplined focus on capital allocation involving acquisitions to support our portfolio as well as increasing returns to shareholders through buybacks. These actions are aligned with our strategy to strengthen our position for more growth in 2020 and the coming years in line with our new mid-term targets out to 2023.

With that, I'd like to hand back to John and the operator for the Q&A session. Thank you.

JOHN GILARDI:

With that, I would like to close this conference call and thank you for your participation. If you have any questions or comments, please do not hesitate to contact us.

Thank you.