Q1 2022 Accuray Incorporated Earnings Call
November 3, 2021

CORPORATE PARTICIPANTS

Joshua H. Levine, Accuray Incorporated – CEO & Director
Suzanne Winter, Accuray Incorporated – President
Brandon "Brandy" Green, Accuray Incorporated – Interim Chief Financial Officer
Ken Mobeck, Accuray Incorporated – VP of Finance & Investor Relations

CONFERENCE CALL PARTICIPANTS

Michael Cox , Lake Street Capital Markets
Joshua Jennings, M.D., Cowen
Anthony Petrone, Jefferies LLC

PRESENTATION

Operator

Good afternoon and welcome to the Accuray Reports First Quarter Fiscal 2022 Financial Results Conference Call. All participants will be in listen-only mode. After today's presentation, there will be an opportunity to ask questions. Please note, this event is being recorded.

I would now like to turn the conference over to Ken Mobeck, Vice President of Finance and Investor Relations. Please go ahead.

Ken Mobeck, Accuray Incorporated - VP of Finance & Investor Relations

Thank you, Anthony and good afternoon, everyone. Welcome to Accuray's Conference Call to review financial results for the first quarter of fiscal year 2022 which ended September 30, 2021. During our call this afternoon, management will review recent corporate developments. Joining us on today's call are: Josh Levine, Accuray's Chief Executive Officer; Suzanne Winter, Accuray's President; and Brandy Green, Accuray's Interim Chief Financial Officer.

Before we begin, I would like to remind you that our call today includes forward-looking statements. Actual results may differ materially from those contemplated or implied by these forward-looking statements. Factors that could cause these results to differ materially are set forth in the press release we issued just after the market closed this afternoon as well as in our filings with the Securities and Exchange Commission. The forward-looking statements on this call are based on information available to us as of today's date and we assume no obligation to update any forward-looking statements as a result of new information or future events, except to the extent required by applicable securities law. Accordingly, you should not put undue reliance on any forward-looking statements.

A few housekeeping items for today's call. First, during the Q&A session we request that participants limit themselves to two questions and then re-queue with any follow ups. Second, all references we make to a specific quarter in the prepared remarks are to our FISCAL year quarters. For example, statements regarding our "first quarter" refer to our FISCAL first quarter ended September 30, 2021. Additionally, there will be a

supplemental slide deck to accompany this call, which can be accessed by going directly to Accuray's investor page at investors.accuray.com.

With that, let me turn the call over to Accuray's Chief Executive Officer, Josh Levine. Josh?

Joshua H. Levine, Accuray Incorporated – Chief Executive Officer

Thanks Ken, and thanks to everyone joining us on today's call. I'm joined today by Suzanne Winter, our President and Brandy Green, our interim CFO.

By any measure, Accuray had a very strong fiscal first quarter. Our performance reflects the visible impact of the investments in innovation we have made to our product portfolio, how those new technologies are being received by customers across the world and a laser like focus on commercial execution, ALL of which are driving accelerated revenue growth in our business.

Revenue for the quarter came in at $107.4 million, which translates to 26% year-over-year growth, and represents the largest fiscal first quarter revenue number the Company has ever recorded. Gross order volume for the quarter was $70 million which translated to 39% year-over-year growth. While Suzanne will provide more details regarding regional contributions during her prepared remarks, I can confirm that the strength in orders and revenue results were reflected across ALL of Accuray's operating regions. Underpinning this strength is the impact of our latest Radixact technology upgrades. ClearRT™, our helical kVCT imaging platform and Synchrony®, our real time motion tracking and beam delivery adaptation capability. We have seen significant customer interest in both of these technology additions and very strong attachment rates for both, with new Radixact orders as well as upgrade activity for installed base systems. The cadence of our new technology innovations is continuing to drive both current, and we believe, future growth in our business.

We continued to see strong contribution from our China JV during Q1. China gross order volume for fiscal year Q1 was $16.3M representing 139% growth versus prior year and we generated revenue of $25.5M which represented YOY growth of 732%. Additionally, we continue to make good progress on our Tianjin produced Type B product and are on track to launch a phased market introduction in the summer of calendar year 2022 with subsequent shipments expected pending regulatory clearance by the end of that year.
We continued to see strong contribution from our China JV during Q1. China gross order volume for fiscal year Q1 was $16.3M representing 139% growth versus prior year and we generated revenue of $25.5M which represented year-over-year growth of 732%. Additionally, we continue to make good progress on our Tianjin produced Type B product and are on track to launch a phased market introduction in the summer of calendar year 2022 with subsequent shipments expected pending regulatory clearance by the end of that year.

Last week, we participated in the ASTRO Conference in Chicago. This was the first in-person opportunity to interact with the US Radiation Oncology community in 24 months. Accuray had a very strong customer turn out at the meeting as well as strong interest and participation at our Investor Event.

As we shared in our ASTRO Investor Day presentation, we are excited about the momentum and progress we see occurring with our business today as well as the long-term growth opportunities we have in front of us. We are launching important technology upgrades across both of our platforms that are designed to

further enhance CURRENT treatment capabilities in delivering hypo and ultra-hypofractionated SRS and SBRT more effectively, safely, and efficiently.

And now I'll turn the call over to Suzanne Winter for some more details on commercial highlights during the quarter.

Suzanne Winter, Accuray Incorporated – President

Thank you, Josh. We are very pleased with our first quarter performance with 32 new system orders and with all 4 Regions executing extremely well. The Americas region led the growth with greater than 200% growth in order volume driven by strong customer demand for ClearRT and Synchrony as differentiating technologies that will allow them to provide ultra-hypofractionated SBRT and IMRT treatments for their patients and compete effectively within the new RO-APM reimbursement environment. Our results give us confidence of two things one, that we are beginning to see market recovery in capital equipment budget spend with some pent-up demand from US reflected in Q1 results and two, the positive impact of commercial initiatives we are driving in this important region.

In the EIMEA region, highlights include a 7-system Radixact win from our distribution partner in Turkey which is building an oncology network which will strengthen our market position in this sub-region and expand access to new markets leveraging Radixact helical delivery platform as a differentiated capability compared to conventional C-arm radiation therapy systems. Japan continued to deliver orders growth with 28% YOY growth within the quarter with key competitive wins at Shinshu and Nagoya University. Finally, our APAC region orders grew 67% YOY driven primarily by outstanding commercial execution in China with 8 new systems including 3 Type A and 5 Type B. Outside of China, we won a second trade in trade up to Radixact at the Royal Brisbane Women's Hospital which will become a strong reference site in ANZ sub-region.

We expect Q1 order growth to significantly outpace global market growth and will result in market share gain, especially in the US market. Our new product introductions drove the momentum with 15 new ClearRT orders bringing the cumulative orders to 59 since we began market launch less than a year ago. Approximately 50% of new Radixact system orders purchased ClearRT as an option on new systems as well. Additionally, our commercial focus on upgrading our aged installed base to the latest performance capabilities is showing results with 54% of developed market orders and 60% of US orders being comprised of trade-in trade-up orders of our existing installed base.

As you heard from Josh, revenue growth for the quarter was outstanding with strong performances from the US and China reflecting some pent up demand which demonstrates that our customers are prioritizing radiation therapy equipment installations. Shipments to China included 9 Type A systems including a CyberKnife® for Beijing Union Medical College and another at Beijing Hospital, both premier institutions highly connected to the China MOH and serving the senior government. We believe these strategic Type A customer installations will help Accuray to continue to drive our solid brand and technology awareness in the China market.

Other key highlights for the quarter included a very successful exhibition at both US and European radiation oncology conferences where we highlighted our latest product innovations. In addition to ClearRT and Synchrony for Radixact, we received 510(k) approval for VOLO™ Ultra, the latest Accuray product enhancement for Radixact's Precision® treatment planning system. VOLO Ultra translates VOLO technology

introduced for the CyberKnife platform to Radixact and increases the speed, ease of use and quality of treatment planning for the Radixact allowing for treatment times of less than 15 minutes and positioning it as a superior workhorse solution within a department. For the CyberKnife, in partnership with RaySearch, we introduced the RayStation for the CyberKnife radiosurgery platform allowing seamless integration within the radiation oncology department and full connectivity across multiple vendor radiation therapy and OIS systems.

Also breaking clinical news from the ESTRO scientific sessions was the 2-year follow up data from the PACE-B trial. PACE-B is a large, multicenter, international trial of patients who have localized prostate cancer. At ESTRO, Dr Alison Tree from Royal Marsden Hospital in London reported on the long-term outcomes of patients treated after 2 years, a timeframe where side effects may occur. Dr. Tree reported that patients treated on CyberKnife experienced more than 2 times LESS urinary side effects than those treated on a conventional linac systems. This important randomized controlled study supports the differentiation of Accuray technology from competitive radiation therapy platforms and underscores the clinical value of proprietary, Accuray capabilities like Synchrony, 4D tumor tracking and adaptive delivery. This Accuray only technology provides the precision that is critical to provide ultra-hypofractionated SBRT treatments so that patients have the best potential for improved outcomes AND quality of life. As we discussed during our Investor Day presentation, the clinical use of ultra-hypofractionated treatments is expected to rapidly grow and randomized studies like PACE-B demonstrate that Accuray's unique high precision technology is differentiated from conventional radiation therapy platforms and positions us to benefit greatly from this growing clinical trend.

In summary, an outstanding start for the organization in Q1 as we execute on our long-term growth strategy, combined with positive signs of improved global capital equipment recovery and an outstanding reception to our new product introductions which are driving customer interest in Accuray technology.

Now I would like to turn the call over to Brandy for her review of the financial details. Brandy?

Brandon Green, Interim Chief Financial Officer

Thank you, Suzanne, and good afternoon, everyone. We started off FY22 with a strong financial quarter. Today I will focus on some of those highlights. As noted, gross orders for the first quarter were $70.0 million dollars, up 39 percent over the prior year period.

From a product mix perspective, the TomoTherapy® platform accounted for approximately 64 percent of gross orders for the quarter and CyberKnife accounted for the remaining 36 percent as compared to historical averages of approximately 60 percent TomoTherapy and 40 percent CyberKnife.

During the first quarter, we had approximately $2.9 million dollars of net cancellations. And we ended our first quarter with backlog of $602.9 million dollars, an increase of 1 percent from September 30, 2020.

Now turning to our income statement.

Total revenue for the first quarter was $107.4 million dollars, up 26 percent compared to the prior year, led by strong year over year growth in Americas and China.

Product revenue for the quarter was $52.8 million dollars, an increase of 69 percent compared to the prior year.

From a product mix perspective, CyberKnife accounted for approximately 47 percent of the revenue unit volume in the quarter, while the TomoTherapy platform accounted for the remaining 53 percent. As a reminder, the mix between CyberKnife and TomoTherapy varies from quarter to quarter. However, historically on an annual basis, our product revenue mix has been approximately 30 percent CyberKnife and 70 percent TomoTherapy for the past several fiscal years.

Service revenue for quarter was $54.7 million dollars, up 1 percent compared to the prior year.

Turning now to gross margin. Overall gross margin for the first quarter was 36.8 percent compared to 41.5 percent in the prior year.

Product gross margin for the quarter was 40.3 percent compared to 41.1 percent in the prior year. At the end of the quarter, per our JV accounting requirements, we deferred product gross margin on 2 systems sold to our China joint venture that have not YET been transacted through to the end customers. Excluding the timing difference on these 2 systems our product gross margin for the quarter would have been 43.5 percent.

Service gross margin for the quarter was 33.4 percent, compared to 41.7 percent in the prior year. There were two primary drivers for the lower-than-planned service margin for the quarter. First, parts consumption and operational costs were higher than normal primarily related to increased system upgrades and travel from increased interest in our latest products. Second, we have experienced increased parts costs and logistical delays with our after-market supply chain due to the effects of the pandemic. Excluding the impact of these challenges, we estimate that our service gross margin for the first quarter would have been approximately 36.5 percent, which is consistent with pre pandemic levels.

Moving down the income statement, operating expenses for the quarter were 37.1 million dollars, an increase of 7.2 million dollars or 24 percent from the prior year. The year-over-year increase in operating expenses was primarily due to the reinstatement of certain actions that were taken to preserve cash in response to the pandemic, including travel, marketing events, and compensation costs, which were reinstated back to near historical levels. We also experienced an increase in commission costs associated with increased revenue.

Operating income for the quarter was $2.4 million dollars compared to $5.5 million dollars in the prior year.

The operating impact of the China JV for the quarter was a loss of $0.3 million dollars. As a reminder, this item is being reported on our income statement as a single line item called, "Gain/loss on Equity Investment" right below our operating income line.

Adjusted EBITDA for the quarter was $5.4 million dollars as compared to $9.0 million dollars in the prior year period. On a trailing twelve-month basis, we have generated $34.3 million dollars in adjusted EBITDA. The reconciliation between GAAP net income and Adjusted EBITDA are described in our earnings release issued today.

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We ended the quarter with $105 million dollars of cash and short-term restricted cash. The decrease in cash from the prior quarter was primarily driven by the payout of employee bonuses earned in the prior fiscal year plus procurement of inventory in anticipation of fulfilling customer orders for the remainder of this fiscal year, both of which are seasonal in nature. Additionally, we paid $1 million dollars on our term loan.

In Q1, we early adopted ASU 2020-06, "Debt with Conversion and Other Options", reclassifying the cash conversion option of our Convertible notes issued in Q4 FY21 of $24.8 million dollars from Equity to Long Term Debt. The underlying value of the convertible notes has remained unchanged from Q4 FY21 when we exchanged most of our convertible notes due 2022 for convertible notes due 2026. The early adoption of this Accounting Standards Update will reduce the accretion of debt discount on the convertible notes into our net income.

And with that, I'd like to hand the call back to Josh for an update on our fiscal 2022 financial outlook. Josh?

Joshua H. Levine, Accuray Incorporated – Chief Executive Officer

Thanks, Brandy. Relative to financial guidance in FY22, we continue to believe our addressable market for global radiotherapy equipment and treatment planning will grow at approximately 4% in FY22. While some uncertainty related to the Covid recovery remains, we believe that we CAN and WILL exceed market growth rates. Additionally, we are expecting revenue to be more balanced between our fiscal halves with increasing contributions from both China and the US due to stronger end of calendar year performance. As such, as previously announced in our preliminary results for the first quarter of fiscal 2022, we are updating our expected revenue guidance to the $420-$427 million range with the midpoint of that range representing 7% year on year growth versus FY21. For FY22 adjusted EBITDA, our expected range is $33-$35M. We continue to believe that our FY19 adjusted EBITDA finish of $23.7M is the best comparison to our forward guidance, as it represents the last FULL pre-Covid year end adjusted EBITDA reference point. As you are aware, we have had the last two fiscal cycles impacted by COVID related spending cuts and aggressive cash preservation actions that made comparability against fiscal 2021 unusually challenging, especially related to adjusted EBITDA. We continue to demonstrate material improvements in operating leverage created over the past two fiscal cycles mainly within SG&A allowing us to increase our planned R&D spend in FY22 focused on accelerating top line revenue growth.

And with that, operator, we're ready to open the line for questions.

QUESTION AND ANSWER SECTION

Operator

Our first question comes from Brooks O'Neil with Lake Street Capital Markets. You may go ahead.

Question - Michael Cox: Hi. This is Michael Cox filling in for Brooks O'Neil. My first question, I'm hoping that you can provide some details on where you think hospital systems are in terms of preparedness for the new RO-APM reimbursement models.

Answer – Joshua H. Levine: Mike, can I ask you to restate that, please? I didn't hear the whole question.

Question - Michael Cox: Yes. I'm hoping that you can provide some details on where you think hospital systems are in terms of preparedness for the new RO-APM reimbursement model.

Answer – Joshua H. Levine: I think, quite frankly, it varies across the board. I think that there are some institutions that have been more rapid in embracing hypo and ultra-hypofractionation. They're larger utilizers from a product technology and mix case mix standpoint of SBRT in general. I think they by nature or by kind of, their more proactive approach are probably better prepared in the current environment for what's coming in January of 2022. I think there are others that are probably not as prepared. And as you might imagine, those represent really ideal targets for us to be telling our story about why the Accuray product lineup is really, really uniquely positioned to be able to assist in this transition to the RO-APM.

Question - Michael Cox: Thank you. And an additional question is with the current labor market has Accuray been impacted with any worker shortages at all?

Answer – Joshua H. Levine: No, not from an operational standpoint. Again, the headwinds that people see now related to labor challenges and supply chain, etc. We're cognizant of that. We have not really had significant problems in those areas. We continue to execute well, both Suzanne and I have terrific faith in our operations team. And so no, we really haven't seen anything, Mike that that gives us pause or concern at this point.

Question - Michael Cox: Okay, that's helpful. And then last question for me is, are you seeing any disruptions due to the supply chain? And do you have any plans on how do you combat these disruptions if there are any?

Answer – Joshua H. Levine: Again, I mean, there's really no company that you can see or look at today that isn't feeling some impact of these macro level kind of trends. But again, we are working diligently. Our ops team is working diligently. Our sourcing team is working diligently to make sure that we can continue to supply, continue to install equipment and be ready to install equipment and recognize revenue and we're really proud and excited about the work that they're doing in keeping pace with these kind of the macro level headwinds that people are seeing.

Question - Michael Cox: Perfect, Thank you for taking my question and congratulations on a great quarter.

Answer – Joshua H. Levine: Thank you.

Operator

Our next question comes from Josh Jennings with Cowen. You may go ahead.

Question – Joshua Jennings: Hi good afternoon. Congratulations on a strong start to fiscal '22. Just two questions, follow-up from the ASTRO Investor Day. The first is -- it's great to hear about the progress and the plans in your journey towards a true online adaptive solution, and you talked about two parallel paths of development, an internal one with your PrecisieART® and also the collaboration with RaySearch. And just wondering, as we think about this development path over the next 12 to 18 months, how should we be thinking about updates to the investment community on the progress there. And are there any key milestones we should have on our radar?

Answer – Suzanne Winter: Yes. I don't know that there are any key milestones that you need to have on your radar but I mean, it is our goal, especially based on the very positive feedback of what we did show to customers at ASTRO, that we're on the right track. We are pursuing, again, a solution for our customers that have RaySearch treatment planning as well as customers that have our Precision treatment planning. We think that the basis of our advantage will be the use of ClearRT and Synchrony as inputs into the online adaptive and that's something that's unique to the industry. And also, we got great feedback in terms of what within the market is a vulnerability of current offerings. And so our goal is to improve upon what is available to the market at this time. So I would say, no, our overall goal is, again, to have something at ASTRO next year.

Question – Joshua Jennings: Fantastic. And then just one follow-up. As we're all looking to try and value the China JV and as that opportunity is and that collaboration is going to be unleashed in 2022, I think one of the underappreciated elements is the Type B system and the opportunity that Accuray has to sell that China manufactured Type B system into other global value segments. You touched on that during the Investor Day, but I was hoping you could build a little bit on that $300 million annual opportunity that you cited. And just where does Accuray stand today in terms of selling into that global value segment with the TomoH or ONRAD systems and our assumption is that it's -- it's de minimis or immaterial impact to your orders and sales. But just wanted to get a sense of the baseline and then potentially how you see this Type B system manufacturing in China driving penetration in that $300 million annual opportunity. Thanks for taking the questions.

Question – Suzanne Winter: No, Josh thanks for the questions. Absolutely. The market that we talked about for a value segment product is incremental to what we're participating in now. The $300 million that we talked about at Investor Day was really the annual opportunity in two locations: India and also Brazil, where we think that both of those segments, there's a larger market opportunity that we just haven't been able to participate in. And so while we are on track with our Type B product for China, we do think that, that same sort of a future set will do very well in other value segment markets. So the $300 million we talked about, really, I think, is tip of the iceberg in terms of emerging market opportunity but those are two places that we'll focus on.

Question – Joshua Jennings: Great. Thanks for that answers.

Operator

Our next question comes from Anthony Petrone with Jefferies. You may go ahead.

Question – Anthony Petrone: Great and thanks for getting us in queue here. Maybe a follow-up to Josh's questions on neurosurgery specifically. And when we think about that opportunity, just wondering what the investment behind neurosurgery will be just as you referenced at Analyst Day that would be my first question. And then the second question would be on just oral bundle, any details from last night's announcement that were surprised or is everything, sort of, as planned? Thanks.

Answer – Josh Levine: Yes. Anthony, Suzanne and I are going to divide and conquer. I'll take the second question which is the RO-APM update. So I think the big takeaway was they did confirm that they are going forward on January 1. That one -- there -- I think there might have been some continued speculation out there about given COVID environment, et cetera, was that going to happen? And the answer is they are

going to push the start button come January 1. There were some elements that were also part of the information release that gave them some latitude in certain data collection activities. You'll remember that one of the components of the RO-APM was a quality system, a quality metrics measurement that was going to be self-reported. Again, I think because of more than anything else, probably the COVID environment and that they're considering that or kind of, defining that as a public health emergency that they've relaxed the requirements for the collection and submission of those quality measures.

And so they've given kind of, this first year of the model, they've given it -- they relaxed the requirements on that piece. The 2% payment fee withhold, again, that was tied to quality measures was also relaxed. So there's been a little bit of a, I'll call it, a reprieve, if you will, on that piece of the fee schedule. Again, those were probably -- I think the last piece of the three was the requirement around the conducting of peer review audit and feedback on treatment plans specifically. They've also made that optional in this first year of the model. So you've got those, kind of, provisions that they've made allowances for, again, given kind of probably most related to the COVID environment but the program is going to start-up on January 1. We think that that's important for a variety of reasons and we like how we're positioned, given where our product lineup is and what's going to be -- we think is going to be important to customers from a clinical practice standpoint under this new model.

Question – Anthony Petrone: Thank you. And then the follow-up is just on neurosurgery, the investment there.

Answer – Suzanne Winter: Yes. So Anthony, so yes, what we talked about at Investor Day, again, an incremental market opportunity in neurosurgery. We talked about a total potential market of $600 million. And really, that represents a replacement market opportunity for aging Gamma Knife that we think through 2026, there'll be approximately 180 systems that are going to get to greater than 10 years and we'll be looking for trade-out. The CyberKnife S7™ now with what we showed with Brainlab, having a treatment planning and contouring interface that is familiar to neurosurgeons, we believe, will be a competitive advantage. The fact that the CyberKnife treats both brain and spine and Gamma Knife only does brain. And also, we think, an improved patient experience without the use of a head frame will be preferred and will put us in a strong competitive position to be able to penetrate some of these replacement opportunities.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Josh Levine for any closing remarks.

Joshua H. Levine, Accuray Incorporated – Chief Executive Officer

Thank you operator. I'd like to thank the entire Accuray team for their continued focus and commitment to great operational and commercial execution. Beyond the tremendous contribution by our team, the clinical and portfolio impact related to our most recent innovations have resulted in improved competitive positioning for Accuray products. As a result of these factors I believe the business is positioned to grow at the fastest rate we have in over a decade and I've never been more excited about the future of Accuray as FY22 unfolds. We look forward to speaking with you again in January associated with our fiscal second quarter earnings release.

Operator

The conference is now concluded. Thank you for attending today's presentation. You may now disconnect.

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