ACCURAY

Q2 2021 Accuray Inc Earnings Call

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CORPORATE PARTICIPANTS

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- Ken Mobeck, Accuray Incorporated - VP of Finance & IR
- Shigeyuki Hamamatsu, Accuray Incorporated - Senior VP & CFO
- Suzanne Winter, Accuray Incorporated - Chief Commercial Officer and Senior VP of R&D

CONFERENCE CALL PARTICIPANTS

- Anthony Charles Petrone, Jefferies LLC, Research Division - Healthcare Analyst
- Brooks Gregory O'Neil, Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst
- Jason Hart Wittes, Northland Capital Markets, Research Division - MD & Equity Research Analyst
- Marie Yoko Thibault, BTIG, LLC, Research Division - Director & Digital Health Analyst
- Neil Chatterji, Cowen and Company, LLC, Research Division - VP

PRESENTATION

Operator

Good afternoon, and welcome to the Accuray Second Quarter Fiscal 2021 Financial Results Conference Call. (Operator Instructions) Please note, this event is being recorded.

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

Ken Mobeck, Accuray Incorporated - VP of Finance & IR

Thank you, Gary, and good afternoon, everyone. Welcome to Accuray's conference call to review financial results for the second quarter of fiscal year 2021, which ended December 31, 2020. During our call this afternoon, management will review recent corporate developments.

Joining us on today's call are Josh Levine, Accuray's President and Chief Executive Officer; Shig Hamamatsu, Accuray's Senior Vice President and Chief Financial Officer; and Suzanne Winter, Accuray's Chief Commercial Officer and Senior Vice President of R&D.

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 laws. Accordingly, you should not put undue reliance on any forward-looking statements.

Two housekeeping items for today's call. First, during the Q&A session, we request that participants limit themselves to 2 questions and then requeue 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 second quarter refer to our fiscal second quarter ended December 31, 2020.

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

Joshua H. Levine, Accuray Incorporated - President, CEO & Director

Thanks, Ken, and thanks to everyone joining us on today's call. Accuray's fiscal 2021 second quarter performance continues to reflect the positive momentum our business is making despite the headwinds created by the COVID-19 environment.

Highlights from our second quarter performance include the beginning of system revenue conversion related to the China Type A licenses awarded to Accuray Systems, receiving 510(k) approval for ClearRT™, our Helical kVCT imaging on Radixact® and the continued adoption of our latest innovations like Synchrony®, real-time motion tracking and delivery adaptation on Radixact and our latest generation CyberKnife® S7™ System.

Revenue for the quarter came in at $97.5 million, which included approximately $21 million of China-related system revenue. The bulk of the China-related system revenue recognized in the second quarter represents the beginning of revenue conversion related to Type A licenses awarded to Accuray Systems in the past 18 months, which have an aggregate estimate value of approximately $150 million. While the number of Type A system shipments will vary from quarter-to-quarter, we currently expect revenue related to the remainder of the Type A licenses will be recognized over the course of the next 18 to 24 months.

Regarding the Type B product segment, our China JV continues to make operational progress in advancing the manufacturing validation and qualification process, and we believe we are on track to have our China-

manufactured Type B product ready for market introduction in approximately 18 months.

Gross order volume for the quarter was $75.4 million, which while down globally versus Q2 of the prior fiscal year due to COVID headwinds, was in line with our internal expectations. As we had shared in our first quarter earnings call in October, this was expected as we highlighted the tough comparisons to the prior year, driven by Type A orders in China during Q2 of the prior fiscal year, coupled with COVID-related headwinds in the Americas and EMEA regions during the current fiscal year.

Despite those challenges, we saw positive order growth in Japan, where gross orders grew 10% year-over-year primarily driven by strong Radixact demand as well as new technologies such as Synchrony on Radixact. On a global basis, approximately 50% of new Radixact orders during the quarter included Synchrony, which is a significant increase from prior year, and we believe this increase demonstrates that our customers see true clinical value in Synchrony's proprietary real-time motion tracking and delivery adaptation capability.

With respect to CyberKnife, we saw a 17% unit volume increase year-over-year, driven by S7 orders in the Americas and EMEA regions. From a financial perspective, we continue to see positive momentum in both operating and financial leverage from the cost management and cash preservation decisions we initiated during the initial stages of the COVID pandemic.

With the improved operating leverage that we are seeing, we will be increasing our investments in R&D, which will bring the spending run rate back to pre-COVID levels of investment.

On the product innovation front, during the quarter, we announced that we had received 510(k) clearance for ClearRT, our Helical kVCT imaging platform for the Radixact System. This regulatory approval paves the way for 2 important milestones in our phased product launch. First, we can now obtain customer clinical evaluation site feedback and generate case studies demonstrating the impact of ClearRT on treatment-related decision-making. Secondly, we look forward to gaining additional global regulatory clearances like CE Mark and Shonin in Japan, in preparation for a broader commercial launch, which we anticipate will take place towards the end of this fiscal year.

ClearRT combines the Radixact System's unique TomoTherapy® helical platform with kVCT imaging capability providing near diagnostic quality image resolution, the longest transverse field of view and best-in-class image acquisition speed that allows clinicians to acquire uniform high-quality images during the treatment. We expect that ClearRT, combined with our Synchrony motion tracking and real-time delivery adaptation on the Radixact platform, will help to

further advance the overall functionality and clinical capabilities of Radixact and its strategic positioning as a workhorse system.

We believe that the significant technology additions we are adding to our current product portfolio are well aligned with CMS' radiation oncology alternative payment model, which is now scheduled to go into effect beginning in January of 2022. Accuray has been a pioneer in high-precision technologies that enable hypo and ultra hyperfractionation, and we believe that the innovations we are bringing to the market will be a catalyst for long-term growth and ensure that our delivery platforms maintain their position as a gold standard choice in hyperfractionated SRS and SBRT treatments.

And with that, I'll turn the call over to Shig to review our Q2 financial results in greater detail. Shig?

Shigeyuki Hamamatsu, Accuray Incorporated - Senior VP & CFO

Thank you, Josh, and good afternoon, everyone. I'll begin with some additional details on our financial performance for the second quarter and then focus on certain highlights for the period.

Gross orders for the second quarter were $75.4 million as compared to $98.6 million in the prior year. As we generated double-digit gross order growth in the last 2 fiscal years due to pent-up demand for China Type A system, triggered by the initial announcement of Type A quota back in October of 2018, we had anticipated that we would be focusing more on converting existing Type A orders to revenue this fiscal year as the volume of new China orders normalize, which is what we saw occur in the second quarter. In addition, we continue to see some headwinds due to the pandemic, particularly in the U.S. region, which has affected the timing of order placement in the near term.

Looking ahead to the third quarter, we expect to see a similar challenging year-over-year comparison for gross orders. The prior year third quarter included $25 million of Type A orders which is expected to be meaningfully lower in the third quarter of this fiscal year for the same reasons I just stated. We also anticipate our gross order volume in the second half of this fiscal year to be weighted more towards the fourth quarter, although we do anticipate a sequential increase in order volume from the second quarter to third quarter.

From a product mix perspective, the TomoTherapy platform accounted for approximately 55% of order unit volume for the quarter and CyberKnife accounted for the remaining 45%. As Josh highlighted earlier, we saw a strong innovation- driven order momentum during the second quarter, where we saw a significant year-over-year order growth for both Synchrony on Radixact as well as CyberKnife S7.

Net age-outs for the quarter were $35 million and included $13 million of age-in activities during the quarter. As expected, we saw a higher-than-normal level of age-outs during the quarter as timing of revenue conversion was impacted by the pandemic in all regions with the exception of China. However, $13 million of age-ins during the quarter represented the highest quality age-in activity we've ever reported.

Although the depth and extent to which COVID-19 will impact individual markets could vary based on a number of factors, we expect to see a higher-than-normal level of age-outs for the second half of this fiscal year, due to this pandemic driven timing disruption.

During the second quarter, we had no cancellations, and FX and other adjustments totaled approximately $2 million. As a result, on a net basis, we generated $42 million of orders in the second quarter. We ended the second quarter with a backlog of $596 million, which is an increase of approximately 11% from December 31, 2019.

Turning now to our income statement. Total revenue for the second quarter was $97.5 million and included a significant year-over-year increase in China system revenue, which was offset by year-over-year revenue decline in other regions, primarily due to the impact of the pandemic. Product revenue for the quarter was $41.8 million and included $21 million of system revenue to China, of which $18 million were Type A products.

From a product mix perspective, CyberKnife accounted for approximately 30% of the quarter's revenue unit volume, while the TomoTherapy platform accounted for the remaining 70%. Service revenue for the quarter was $55.7 million, an increase of 1% from the prior year.

Turning now to gross margin. Our overall gross margin for the quarter was 41.9% compared to 38.4% in the prior year. Product gross margin for the quarter was 44.7% compared to 44% in the prior year. The second quarter product gross margin represented a meaningful sequential improvement from the first quarter product gross margin of 41% as we saw a higher mix of CyberKnife units during the quarter.

Service gross margin for the quarter was 39.8% compared to 33.9% in the prior year. As a reminder, prior year Q2 service margin included the impact of a higher-than-normal level of service parts consumption. Our operations and service teams have done a great job of normalizing parts consumption in the past 4 quarters, which contributed to a material year-over-year improvement in service gross margin. Additionally, Q2 service margin benefit from higher upgrade revenue as well as continued benefit from reductions in travel and other operating costs due to the pandemic.

Moving down the income statement. Operating expenses for the quarter were $32.6 million, a decrease of $1.6 million or 5% from the prior year. The year-over-year decline in our operating expenses was primarily driven by the actions we implemented in response to the pandemic, which included physician eliminations as well as curtailment of costs associated with the impact of COVID-19, particularly travel, marketing events and related expenses.

As we look forward to the second half of this fiscal year, we anticipate our quarterly operating expense run rate will start to normalize in the range of $35 million to $37 million as we restore certain expenses and continue to invest in our R&D pipeline. In addition, the higher operating expense run rate in the second half of this fiscal year is consistent with the seasonality we have seen in the past fiscal cycles.

Operating income for the quarter improved $4.6 million to $8.2 million compared to $3.6 million in the prior year. This represented the fifth consecutive quarter of GAAP operating income generation, and we have generated $27 million of operating income for the trailing 12 months period measured from December 31, 2019.

While our operating income benefited partially from cost management actions taken in response to the pandemic, we expect our improved operating leverage will position us well in the post-COVID environment. The operating impact of the China JV for the quarter was an income of $1.1 million. This item is being reported on our income statement as a single line item called gain or loss on equity investment right below our open income line.

As our China joint venture continues to ramp its operational and commercial activities, we expect our share of JV's quarterly income or loss will continue to fluctuate in the near term, and we expect our share of JV's operating impact will be a small loss in the second half of this fiscal year.

Adjusted EBITDA for the quarter was $13.5 million compared to $7.1 million in the prior year. On a trailing 12-month basis, we have generated $44 million of adjusted EBITDA. The adjustments between GAAP net income and adjusted EBITDA outlined and quantified in our earnings release issued today.

Our cash and short-term restricted cash position improved $7 million from the start of this fiscal year to $116 million as of December 31, 2020, despite paying down $10 million of term loan as the team continues to focus on managing our working capital. We also generated $15 million of free cash flow in the first half of this fiscal year.

As we look ahead to the second half on revenue front, we remain cautious on revenue conversion timing given the current state of the pandemic, although we believe the visibility we are gaining on China Type A revenue conversion will

soften the potential impact of the pandemic-driven timing disruption. As we manage our near-term headwinds and revenue conversion, we are continuing to focus on operational efficiency, continued investments in innovation, margin expansion and working capital management. We are also focused on inventory of supply chain management as we execute on China Type A revenue conversion while maintaining appropriate levels of inventory.

With that, we're ready to open up the call for your questions. Operator?

QUESTIONS AND ANSWERS

Answer – Operator: (Operator Instructions) Our first question comes from Josh Jennings with Cowen.

Answer – Neil Chatterji: This is actually Neil on for Josh. The first question I had was just, I guess, around ClearRT. Now that it's approved, could you maybe just lay out kind of at a high level what the path forward is towards having, I guess, a broader adaptive therapy solution? And what steps would be to get there?

Answer – Suzanne Winter: Sure. Josh, it's Suzanne. Just a little bit about our phased product introduction. We shipped to our clinical site for our Phase 1 part of the introduction. We're getting feedback from our clinical sites, then we'll go to a broader introduction in Q4. And we hope to follow-up with CE Mark and Shonin so that we can address broader markets.

ClearRT is really going to be the fundamental difference and backbone of any adaptive therapy that will be developed in our innovation pipeline. One of the things we've certainly been watching to take a look at existing adaptive therapies that are out there now and still very -- well, a good idea and a good first path at adaptive therapy changes is still is burdensome from a workflow standpoint and also very resource intensive.

So from that standpoint, I think we are happy to be a fast follower here and take a look at what we can improve on the next phase to ensure that it is more clearly adopted by clinicians.

Answer – Neil Chatterji: Great. Just a second question. Just in terms of the joint venture, the sales force team and leadership that's currently under CIRC, how is that, I guess, positioned versus the prior distributor sales force in terms of offering the current Type B offerings for ONRAD™ and TomoH®? Our thought is that, that would be a stronger effort versus prior, but just wanted if you can check that.

Answer – Joshua H. Levine: We agree, Neil. So again, we're appreciative that the legacy distributor, TomoKnife, had done a terrific job looking back over the years of positioning our brands. What CIRC, as a joint venture partner, really brings us is strategic market access in a pretty powerful way. As you've heard us talk about,

they are a market-leading company in medical ready isotope production and sales, and they've got active customer relationships in probably 7,000 or 8,000 hospitals across the country.

So they are both a manufacturing partner for us in terms of the on the ground product being produced on the Type B in Tianjin. But they also are, we think, a very powerful partner in the context of commercial activity, strategic market access and visibility, if you will, across more than just the major population centers because kind of the big upside here for us, when we think about the Type B product, is the opportunity that exists in small to medium-sized facilities out in the provinces. And that's where CIRC has an existing strength in terms of market position, customer relationships that will be very valuable in the context of helping us ramp up the Type B product.

Answer – Operator: The next question is from Brooks O'Neil with Lake Street Capital Markets.

Analyst: Brooks Gregory O'Neil, Lake Street Capital Markets, LLC, Research Division - Senior Research Analyst

Question – Brooks Gregory O'Neil: Congratulations on what I think is a terrific quarter in light of the challenging conditions.

Answer – Joshua H. Levine: Thanks, Brooks.

Question – Brooks Gregory O'Neil: So I was hoping to just get a little color. Obviously, we see the COVID impact underlying some of the numbers. So if you could just maybe you, Suzanne, Josh, could walk us around the key markets outside of China in terms of what you're seeing right now? And then specifically, I'm curious about the U.S. market and how you see the impact of the pushout of the APM until the start of the next year impacting the business in the next 12 months?

Answer – Joshua H. Levine: Yes. Brooks, it's Josh. I'll take those. So COVID, let's just start at home, so to speak, in terms of the Americas region, primarily being U.S. We're in a different place than we were, let's say, during the summer or at the end of the summer when hospitals had been locked down for a period of time, in some cases, an extended period of time, and then we're opening back up late summer, I'll call it, early fall. We have not seen widespread visibility of lockdowns in the U.S. market, similar to that existed last year. So I don't think we're, at least by visible signs, we're not there where we were last year.

With that said, it's -- this is -- the intensity of the COVID cases and ICU capacity varies pretty highly from area to area or region to region across the country. And there's -- that variability, if you will, really kind of makes it difficult to identify in a

broad sense painting an outcome or recovery time lines with a single brush, so to speak.

I think that if -- one thing I can confirm is cancer patients are being treated. You've heard us say before that cancer is not taking a vacation for the coronavirus, and that is still very much the case. And we have active patient treatment taking place in our install base throughout the country. And so there's really -- it's a -- I think that it's likely that we will continue to see, let's say, for the first half of calendar 2021, a slowdown and a continued slowdown in terms of timing or go-slow approach from an order activity standpoint.

And I'd say what I just described for the Americas region is reasonably similar in the other developed markets. So I would say fairly consistently similar with regards to Western Europe, the Eurozone markets primarily. And so I'd say the Americas and EMEA are kind of in that same place.

We talked in the prepared remarks about order activity in Japan, which is really showing a remarkably robust, I think, trajectory or at least backdrop, again, given an environment where they're seemingly as challenged with the COVID situation as anywhere else geographically, but there are clearly decisions being made there with regards to allocation of resources around capital expenditures, et cetera. So we're encouraged by that.

The second part of your question, I believe, Brooks, was around the APM model. And while we're -- we understand the reasons behind the delay in implementation for the APM model until January 2022. We don't think it affects longer term the overall trajectory or the impact that, that decision will have on our business. And you've heard us talk about before the fact that the business is coming based on the reimbursement changes. The business is moving in the direction of hypofractionation and ultra hyperfractionated treatment delivery. Our portfolio is getting stronger by the quarter as you've seen, the cadence of new innovations that we're launching. And we think we're extremely well positioned going forward in the context of the environment that the APM implementation will continue to or impact in a positive sense relative to its impact on us.

Question – Brooks Gregory O'Neil: That's great. That's great color. If I could just ask a second probably 2-part question, I apologize. But can you give us a little more color on the China revenue? How many systems kind of what you expect over the next few quarters on the Type A side? And I know you mentioned the commentary about joint venture production 12 to 18 months out. Do you expect any milestones on the Type B side in the next, say, 12 months?

Answer – Joshua H. Levine: Yes. Okay. So on the quarter we just reported, we took 4 orders on the order side from the China JV. They were 2 Type A and 2 Type B. On the revenue side in the quarter, we booked 9 systems, 7 were Type A,

2 were Type B. And of the 7 that we -- on the revenue side that we booked, I think -- I know we had CyberKnife and TomoTherapy and Radixact products as well as 2 TomoH devices on the Type B side.

So as we've talked before, it's not as if we don't have anything to sell and respond to the market with regards to Type B today, we've got ONRAD, we've got TomoH. Both are active in the qualification universe, if you will, of the Type B approved products. So we're continuing to see some activity there. And I would expect that, that will continue which will be helpful, quite frankly, until we're ready to have our Tianjin-produced product coming out of the factory with CIRC in about 18 months.

Question – Brooks Gregory O'Neil: Great. Any color on Type B? And what you expect from Type B in terms of orders ramping up or whatever?

Answer – Joshua H. Levine: Well, I mean, again, we're taking Type B orders today with our current product offering. So the products that I mentioned before, TomoH and ONRAD are active. They're in the approved products list for Type B. The JV and our dealer network there are actively taking and can take orders for those products, and they are doing so. And as you saw in the quarter, and it's been fairly consistent over the last year or so or 18 months, we're showing -- again, it's admittedly modest unit volume level, but we're not a nonpresence, if you will, in Type B today.

We're -- and we'll continue, I would imagine, Brooks, at that pace or cadence, if you will, until we have our own product, the China-produced product available in about 18 months.

Answer – Operator: Next question is from Marie Thibault with BTIG.

Analyst: Marie Yoko Thibault, BTIG, LLC, Research Division - Director & Digital Health Analyst

Question – Marie Yoko Thibault: Congrats on the strong quarter. I may start with a follow-on to Brook's question about the China revenue. Wanted to get a little more insight into how you envision, I guess, kind of the cadence of some of this rolling out? I know you said that there's a total value of $150 million in those orders. So how we should think about kind of the lumpiness or not lumpiness of that revenue recognition as well as kind of the second tranche of awards that you also have in hand?

Answer – Shigeyuki Hamamatsu: Marie, thanks for the question. I'll take that. And yes, so again, we're not going to be able to give specifics on quarterly cadence. But as we said earlier, we think it's going to be a rollout of the remaining revenue

out of the $150 million we talked about over the course of the next 18 to 24 months.

Now as Josh just mentioned, we shipped $18 million of Type A, which was part of the $21 million we talked about. And so what I could probably say is, is it going to be a big fluctuation from quarter-to-quarter in the next few quarters? We're not seeing that necessarily. But again, we do expect the amount or the revenue number of units shipped from quarter-to-quarter vary. So I will just leave it at that, Marie.

Question – Marie Yoko Thibault: Okay. Clear enough. I appreciate that. And then perhaps we could talk a little bit about the replacement tailwinds. You've certainly been vocal about the older age of your installed base. So I'd love to hear what you're hearing from some of your legacy customers who are thinking about replacements and possible timing on when we may see some of that start to turn in a bigger way?

Answer – Suzanne Winter: Yes. Marie, we started to see some of the tailwind even this quarter at 26% of our total orders were trade-in and trade-up. And I think we're excited about the response that we're getting with the introduction in ClearRT. And so I think that with Synchrony is providing a really good rationale for our customers to make the investment to upgrade. So we only expect, as we move forward, that, that percentage may increase as well.

Answer – Operator: Our next quarter is from Anthony Petrone of Jefferies.

Analyst: Anthony Charles Petrone, Jefferies LLC, Research Division - Healthcare Analyst

Question – Anthony Charles Petrone: Maybe a couple on China to stay there, and then a couple on COVID. I guess on the -- I'm going to shift to the spend side, Josh and Shig, just on China, the JV. You mentioned recently at the JPMorgan Conference, you want to add up to an additional 100 head count to the 100 base, get up to 200 by fiscal '23.

I'm just wondering what the cadence of adding those -- adding to the infrastructure is through 2023. Should we expect the bolus near term? Will it be sort of evenly loaded through 2023? And then I'll have 2 follow-ups.

Answer – Shigeyuki Hamamatsu: Yes. Anthony, I'll take that question. Thanks for the question. And I think what we see is more of an even gradual build of that additional head count at the JV level. And just to remind you, as they get at it to JV operations, they don't run through our expenses. It's not going to show up as Accuray's P&L expense in COGS or OpEx rather the impact of that for us would be picked up through the 49% equity interest pickup towards the bottom of

income statement. So I just want to make that clear. And I guess, you have next question.

Question – Anthony Charles Petrone: Sure. And again, well, one would be on the head count adds. I mean I fully understand that there's ownership in the JV, but funding of the new head count, maybe just a refresh on how actually the funding will go and how the funding of growth of the JV will blend those 3?

Answer – Shigeyuki Hamamatsu: Yes. At this point, the best way to think about how to fund that at the JV level is that they are self-funded. And so the initial capitalization was completed when we formed the JV effectively. As you recall, our partner provided the cash capital. We provided the in-kind capital. So they are fully capitalized, and they're going to fund additional head count through their own operations.

Answer – Joshua H. Levine: Anthony, we really don't expect any incremental or surprise capital calls from where we sit today. I mean, again, what Shig just highlighted, I think, is our strong belief, very confident belief that this is self-funded on their end. Just to be more -- a little bit more granular, most of it, if not, the vast majority of all of the commercial operational side of the -- let me back a commercial piece of the infrastructure is actually in place today, full representation, if you will, on the strategic marketing side and sales and marketing side in general.

I think the head count that you'll see added over time now is really more on the operational side with specific emphasis on the manufacturing operation and perhaps some regulatory -- additional regulatory manpower in efforts related to product registration approval and manufacturing qualification and validation approval. So by functional area, it's really heavily indexed to more of the ops, the manufacturing ops and regulatory piece.

Question – Anthony Charles Petrone: Okay. And a follow-up here would be also just, I guess, on the multiyear outlook from a segment basis, you sure have material out there suggesting this can sort of approach the 4,000 linac opportunity in China. And by 2026, when you back out the existing tender, both the 2018 and I guess, the prior 2015 tender, you're looking at almost 2,000 additional units. And so when you sort of think about that multiyear opportunity, where does the confidence come in, in that outlook? And what is the expectation for a follow-on tender from the 2018 one in terms of timing?

Answer – Joshua H. Levine: Well, I mean, I think if you look at traditionally how the government -- the Central Government handles the 5-year planning process, the 14th 5-year plan is probably in development and active process, if you will, from a development standpoint, as we speak. I can't predict when it would be announced, obviously. But we certainly believe that there are -- we know that there are on the Type A side, at least, another, call it, in round numbers, maybe

90, 95 additional Type A devices that were identified in the original quota that will probably roll over -- very certainly roll over into the next 5-year plan, if they're not captured in this 5-year plan.

Although -- we also know that, as we mentioned in the last earnings release, we believe that applications have already been captured online in the Central Government's Ministry of Health Application -- Electronic Application process that would indicate that there are -- there's a third batch of Type A licenses that have been -- applications have been received for and not yet announced, which we believe likely will occur sometime maybe in April, May kind of time frame.

But as you were talking about, the big upside here is Type B. And there would be -- I think every bit of the same kind of unit volume quota impact that we saw in the original quota announcement, which was something that had been, in round numbers, ultimately, increased to about 1,400 Type B devices in the Type B quota. We would think that, at least, that many would be represented again in the next 5-year plan.

So the magnitude of the market opportunity in China is, it can't be overstated. And the fact that we have -- we still believe a very unique strategy in terms of our participation in that market and the value of core segment of the market opportunity there is what gives us, quite frankly, the confidence to feel like we're on the right path.

Answer – Operator: (Operator Instructions) The next question is from Jason Wittes with Northland.

Analyst: Jason Hart Wittes, Northland Capital Markets, Research Division - MD & Equity Research Analyst

Question – Jason Hart Wittes: Just more questions on China. You gave some indication in terms of what the comp was for China revenues last quarter -- or the year ago quarter. Could you tell us what the comp is for the upcoming quarter and for the year for China revenues?

Answer – Joshua H. Levine: Yes. I think we referenced orders against the prior year in...

Question – Jason Hart Wittes: I'm sorry, orders, if you could. Yes.

Answer – Shigeyuki Hamamatsu: Yes. So what I said, I think, Jason, was last year, Q3 -- just bear with me for a second. I believe, last year Q3, we had something like a $25 million of Type A orders last year Q3. So that will be a tough comp for us

again this year. I mean this -- next quarter, excuse me, that was my commentary, I think.

Question – Jason Hart Wittes: Could you also add revenues? I mean you did provide revenues for this quarter. So I'd be curious to know what the revenue contribution was for next quarter and for the year just so we can kind of track the progress of China, which I think is at least the way I'm pretty critical to the outlook for, I guess, most of us here?

Answer – Shigeyuki Hamamatsu: Yes. So again, I don't think we specifically talk about China revenue contribution in the context of last year Q3, Jason. But the way to think about it is we had a small unit of -- B units in last year Q2. So we're talking about the low -- probably mid-single digit China revenue last year, Q3.

Question – Jason Hart Wittes: Okay. And I guess that's kind of the tone for the -- if I look at last year, that was the tone, probably -- the contribution was something in the mid-single digits, is that the right way to think about it?

Answer – Shigeyuki Hamamatsu: That's the way to think about it because, again, we didn't have a Type A revenue as we were waiting for the tender to complete. So we had a small contribution from B units second half of last year.
So that's the way to think about it.

Question – Jason Hart Wittes: Okay. And then looking at the P&L, I guess, you're indicating that OpEx is going to go up in the second half. I assume that's more in the fourth quarter than the third quarter. But I also assume -- can we assume that this is going back to sort of post-COVID levels or is there still going to be -- in those numbers, as you described, is there still a pretty large COVID impact on those -- expected in those numbers?

Answer – Shigeyuki Hamamatsu: Yes. Thanks for the question, Jason. So the cadence of Q3 versus Q4, you're correct. I would expect the Q4 to be higher than Q3, which is the seasonality that we always saw in the past fiscal cycles. And I think the way we think about it in the second half run rate, I said $35 million to $37 million per quarter, it is more normalizing back to what we were pre-COVID.

And if I -- the best way to think about this, Jason, is that I would compare our annual run rate to what we had in FY '19, which is the full pre-COVID fiscal year when we incurred $162 million of OpEx for the entire year. I would say, when we start to run $35 million to $37 million second half of this year, and that will probably equate to the annual run rate of something like $144 million or something like that, which implies that we are still operating even after normalizing coming out of COVID, was probably still operating about 10% below where we were in terms of OpEx pre-COVID cycle.

Question – Jason Hart Wittes: Okay. That's helpful. I'll switch gears, and on ClearRT, Josh, I think you got approved, congratulations. It does seem pretty incremental. But it sounds like it's going to be a controlled launch initially. Is that the way to think about it? And when do we -- when does it sort of go fully out to the field, I guess?

Answer – Suzanne Winter: Yes. So it is a phased launch. And again, we're in Phase 1 of the launch, which is sending to our clinical sites. So the installation is going very well, and we're at the point of just getting clinical evidence as well as finalizing final product parameters. And then we'll go to a full launch, which will be in the Q4 time frame.

Question – Jason Hart Wittes: Q4, okay. And older Radixact machines upgradable to ClearRT as well, and can you give us an indication of kind of what the price bump is for ClearRT?

Answer – Suzanne Winter: Yes. So the ClearRT will be available to the Radixact install base as an upgrade, and it's also available to any TomoTherapy customer. There'll be an upgrade, trade-in, trade-up price as you get to the latest version with ClearRT.

Question – Jason Hart Wittes: So if I have a current system with ClearRT, it's just upgrade, right? It's not a replacement.

Answer – Suzanne Winter: Yes. You are right. It's an upgrade.

Question – Jason Hart Wittes: And do you have an indication of kind of what the ASP is for an upgrade?

Answer – Shigeyuki Hamamatsu: Jason, not yet on ClearRT. So we'll probably, in the next few months, ramping up on commercial activity. So I think we should be able to talk about that a little bit more then.

Question – Jason Hart Wittes: Okay. And then also just related to that, I assume that upgrades are going to be available until that Q4 when the full rollout comes through.

Answer – Suzanne Winter: That's correct.

Question – Jason Hart Wittes: Is that the right way to think about it?

Answer – Suzanne Winter: Yes.

Question – Jason Hart Wittes: Okay. Last question. Just if I think about -- obviously, we're very focused on China here. Japan obviously came in very nicely as well. In terms of more established U.S. and European markets, it sounds like the tone is

that COVID is still largely impacting both the performance there, but also just kind of the visibility for the moment. Is that the right way to think about it?

Answer – Joshua H. Levine: Yes. I would say that, that's a fair representation. I think it's important to note, though, Jason, that we're not seeing orders cancel out of the backlog, okay? So we are not -- again, if you think about where the market was going back to last summer and even into -- in some places in the early fall, I don't see today in the developed market, so call it in the U.S. and Western Europe, I don't see that level of -- again, there isn't any visible signs of a wall-to-wall lockdown in hospitals today.

What's happening is time lines are pushing out. So timelines on projects that are already teed up orders in the backlog, timing for revenue conversion is pushing out. Again, highly variable from institution to institution or region to region. But obviously, we're staying close to all those customers, and we're ready to begin installation and push the go button on any of the or all of those projects that customers are -- when they give us the sign that they're ready to go, we can react quickly. So -- but I think as you've described it, that would be a good representation in terms of how we're thinking about it relative to impact.

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

Answer – Joshua H. Levine: Thank you, operator. In closing, we are pleased with the progress we see occurring with the business despite the challenging environment, and we're strongly focused on taking advantage of the anticipated growth catalysts and opportunities we have in front of us.

During fiscal third quarter, we have a number of investor conferences that we look forward to participating in, including the BTIG Healthcare Conference in February and the Cowen Healthcare Conference in March. Lastly, we intend to report our fiscal 2021 third quarter results at the end of April. Thanks to everyone listening in to today's call.

Answer – Operator: The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.