DCPH 2Q:20 Earnings Conference Call

Operator

Good afternoon everyone, and welcome to Deciphera Pharmaceuticals' second quarter 2020 financial results conference call. Today's call is being recorded. At this time, I would like to turn the call over to Jen Robinson, Vice President, Investor Relations. Jen?

Jen Robinson, VP, Investor Relations

Thank you, Rochelle. Welcome, and thank you for joining us today to discuss Deciphera's second quarter 2020 financial results. I'm Jen Robinson, Vice President, Investor Relations, at Deciphera. With me this afternoon to discuss the financial results and provide a general corporate update are Steve Hoerter, President and Chief Executive Officer, Dan Martin, Chief Commercial Officer, Matt Sherman, Chief Medical Officer, and Tucker Kelly, Chief Financial Officer.

Before we begin, I would like to remind you that any statements we make on this call that are not historical facts are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Examples of forward-looking statements made during this conference call include our expectations for our pre-clinical and clinical programs, our commercialization of QINLOCK, and 2020 guidance. Forward-looking statements made on this call involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we cannot assure you that our expectations will be achieved. Such risks and uncertainties include the potential impact of COVID-19, the execution of clinical trials, the timing of study data, and those set forth

in our most recent quarterly report on Form 10-Q as well as our other SEC filings. We assume no obligation to update or revise any forward-looking statements. Following this call, a replay will be available on the company's website, www.deciphera.com. With that, I will now turn the call over to Steve Hoerter, President and Chief Executive Officer of Deciphera. Steve?

Steve Hoerter, President & CEO

Thank you, Jen.

Good afternoon everyone and thank you for joining us on today's call. Deciphera's mission has always been focused on discovering, developing and delivering important new medicines for the treatment of cancer, and in the second quarter we were proud to announce FDA approval of our first product, QINLOCK, for the treatment of patients with fourth-line GIST. QINLOCK was purpose-built for the treatment of this disease and is the only approved drug in the post-imatinib setting that offers a clinically meaningful overall survival benefit for GIST patients. The FDA approval, and launch, of QINLOCK is an important milestone for the thousands of people in the United States facing a GIST diagnosis, and also serves as validation of Deciphera's novel approach to designing switch control kinase inhibitors.

FDA's approval of the QINLOCK NDA came approximately 3 months ahead of its PDUFA date and was reviewed under the FDA's Real-Time Oncology Review, pilot program with priority review. The QINLOCK NDA was also part of Project Orbis, an initiative of the FDA Oncology Center of Excellence that provides a framework for concurrent submission and review of oncology drugs among participating international health authorities. As a part of this initiative, we recently announced the approval of QINLOCK both by Health Canada and by the Australian Therapeutic Goods Administration. Additionally, as we look to further expand access to QINLOCK outside of the United States, we intend to file a Marketing Authorization

Application with the European Medicines Agency in the fourth quarter of this year. Finally, last month we were excited to announce, along with our partner Zai Lab, that the China National Medical Products Administration, or NMPA, has accepted the NDA for QINLOCK. And, earlier today, Zai announced the QINLOCK has received Priority Review.

Prior to receiving FDA approval, our commercial and medical affairs teams had been working diligently to lay the groundwork and optimize readiness for the commercial launch. Because of their dedication and hard work, we were able to ensure that QINLOCK was commercially available through our limited specialty pharmacy network within one week of approval. During the call today, Dan Martin, our Chief Commercial Officer, will share our initial insights into the commercial launch. While we are still in the early days of the launch, we are very pleased with our progress so far and believe that QINLOCK has the potential to transform the treatment of GIST in the post-imatinib setting.

Beyond QINLOCK, we continue to advance our pipeline of novel switch control kinase inhibitors, and Matt Sherman, our Chief Medical Officer, will discuss in further detail the progress we've made across our portfolio of product candidates including our plans to declare a recommended Phase 2 dose for DCC-3014 in tensynovial giant cell tumor (TGCT) and present additional data from our Phase 1 study in patients with TGCT later this year.

I'll now turn the call over to Dan Martin, our Chief Commercial Officer, to discuss the exciting results for the first partial quarter of our QINLOCK commercial launch. Dan?

Dan Martin, Chief Commercial Officer

Thank you, Steve.

Good afternoon. Today, I'm pleased to share results from Deciphera's first partial quarter as a commercial-stage company as well as initial insights regarding the QINLOCK launch. It's important to recall that QINLOCK was approved on May 15th. Therefore, the commercial results and early launch insights I will share come from just 31 selling days over a period of approximately 6 weeks.

We are very pleased with the results of our first partial quarter of launch. Q2 net product revenue for QINLOCK was $4.8 million. Several important factors contributed to this result:

The first is strong prescriber demand for QINLOCK. Based on feedback from our sales team, market research, and interactions with key opinion leaders, we believe this strong demand was the result of high unmet need in advanced GIST, rapid growth in awareness of QINLOCK, GIST treaters' positive perceptions of the QINLOCK clinical profile and FDA label, and the focus and determination of our customer-facing teams despite the challenging selling environment presented by COVID-19.

Second, we were very pleased to see significant prescriber breadth and diversity. In this initial 6-week launch period, there were more than 100 unique QINLOCK prescribers representing more than 90 unique institutions. Approximately 50% of prescribers and 40% of QINLOCK-treated patients were from community accounts, consistent with our understanding of where GIST patients receive treatment. And nearly 80% of these prescribing institutions had no prior experience with QINLOCK from participation in clinical trials or our expanded access program.

Third, I am pleased to share that our market access team has rapidly achieved broad patient access to QINLOCK. Our extensive launch preparations enabled us to deliver our first patient shipment of QINLOCK

within days of approval. Additionally, our payer-focused efforts have led to broad coverage across both Medicare and commercial payers, including adoption of favorable coverage policies that are consistent with label.

In addition to strong demand, encouraging prescriber breadth, and broad patient access, our Q2 results benefitted from several additional factors. First, our Q2 results included modest revenue associated with patients who switched to commercial drug from our expanded access program in the U.S. The U.S. portion of our expanded access program was closed in May upon FDA approval of QINLOCK. In addition, as with any oral oncology launch, our Q2 product revenue included the impact of initial inventory build within our network of specialty pharmacies and specialty distributors. Inventory held by our channel partners was in line with our days-on-hand targets and we expect this inventory impact to diminish in subsequent quarters. Lastly, during this initial six-week launch timeframe, the percentage of patients receiving free drug under our patient assistance program was lower than our estimate of approximately 20-30%. However, as we communicated previously, this percentage can vary quarter to quarter and, moving forward, we continue to expect approximately 20-30% of patients to receive free drug as part of this program.

Before turning the call over to Matt, I would like to provide an update regarding our experience navigating the unprecedented challenges of the coronavirus pandemic and our expectations regarding its potential impact moving forward. As I reviewed on previous calls, the cross-functional launch team has worked extremely hard to adapt our launch strategies and tactics to a virtual model. This includes developing and deploying remote detailing capabilities and increasing our investment in digital and other non-personal marketing channels. Our early experience is that, while virtual details can be effective, accessing and coordinating the activities of physicians, pharmacists and other critical stakeholders within large, complex

healthcare institutions can be quite challenging and can take longer than usual when required to do so remotely. Additionally, our recent market research with GIST prescribers indicates that GIST patient volume remains below pre-COVID-19 levels and that some GIST treaters may consider delaying treatment switches for advanced GIST patients due to COVID-19-related concerns. Lastly, it remains to be seen what impact the millions of people who are newly uninsured due to pandemic-related job losses will have on the proportion of patients eligible to receive free drug under our patient assistance program. Therefore, while we are very pleased with GIST treaters' initial response to QINLOCK, we also recognize the potential for the continued spread of COVID-19 to impact physician access, GIST patient treatment, and the rate of uptake for QINLOCK in the near-term.

I will now turn the call over to Matt to discuss the progress of our ongoing clinical programs. Matt?

Matt Sherman, Chief Medical Officer

Thank you, Dan.

As Deciphera has transitioned into a commercial-stage company, we have remained deeply committed to furthering our understanding of how QINLOCK may benefit patients beyond our initial approval in fourth-line GIST and in advancing our additional, ongoing clinical-stage programs to create new medicines for patients with significant unmet medical needs.

While our commercial team executes a successful launch, our medical team continues to support the potential of QINLOCK in GIST with a robust publications plan and a life-cycle management strategy, which includes the potential to treat second-line and beyond GIST patients.

In June, results from the pivotal INVICTUS study were published in *Lancet Oncology* highlighting QINLOCK's significant improvement in progression-free survival, or PFS, compared to placebo as well as its clinically meaningful improvement in overall survival along with a well-tolerated safety profile. We also presented additional QINLOCK data from the INVICTUS study demonstrating positive patient reported outcomes results at the ASCO Virtual Scientific Program in May and additional clinical benefit for crossover patients at the ESMO World Congress on Gastrointestinal Cancer 2020 Virtual Meeting in July.

At the upcoming ESMO Virtual Congress in September, we look forward to presenting additional data from the ongoing Phase 1 study of QINLOCK and from the INVICTUS pivotal study in two mini oral presentations. The first presentation is titled *Ripretinib Intra-patient Dose Escalation Following Disease Progression Provides Clinically Meaningful Progression-Free Survival in Gastrointestinal Stromal Tumor in Phase 1 Study*. This presentation focuses on the GIST patients who were enrolled in the dose-escalation and expansion phases across second-, third- and fourth-line treatment who received QINLOCK 150 mg QD. Patients in the Phase 1 study had the option to be dose escalated to 150 mg BID. We will report at the meeting the initial progression-free survival or PFS1 and the subsequent progression-free survival or PFS2 from the date of dose-escalation to second disease progression or death for this subgroup of patients who were dose-escalated to 150 mg BID.

The second presentation is titled *Clinical Benefit with Ripretinib as (fourth-line or greater) ≥4th Line Treatment in Patients with Advanced Gastrointestinal Stromal Tumors (GIST): Update from the Phase 3 INVICTUS Study*. This presentation will highlight updated PFS by blinded independent central review, overall survival, and safety with a new data cut-off of March 9, 2020, which is an additional 9 months of follow-up from the data presented at ESMO last year.

Our team at Deciphera continues to be encouraged by the potential for QINLOCK to meaningfully alter the treatment landscape for the spectrum of GIST patients across multiple lines of therapy. While QINLOCK is being well-received by fourth-line GIST patients and their treating physicians, we look forward to advancing QINLOCK for the treatment of patients with second-line GIST, where we believe it can also provide meaningful benefit.

To that end, we are pleased to report today that we are on track to complete the target enrollment in the fourth quarter of this year in our ongoing INTRIGUE Phase 3 study of QINLOCK compared to the current standard of care, sunitinib in patients with second-line GIST. Currently, there are 122 sites in 22 countries that have been activated in the INTRIGUE study.

We also continue to rapidly advance our next wave of novel switch control kinase inhibitors. First, turning to DCC-3014, our potent and selective inhibitor of CSF1R, we are on track to select a Phase 2 dose level for the treatment of tenosynovial giant cell tumor, or TGCT, and initiate the expansion cohort later this year. We expect to present data from additional patients from the dose escalation portion of the Phase 1 study at a medical meeting in the fourth quarter. As you recall, we presented initial clinical proof-of-concept data in three TGCT patients at the Connective Tissue Oncology Society, or CTOS, annual meeting last year and we look forward to sharing additional data later this year.

Turning to rebastinib, our potent and selective TIE2 inhibitor, we are conducting two clinical Phase 1b/2 studies in combination with chemotherapy, one with paclitaxel and one with carboplatin. At the ASCO 2020 Virtual Meeting in May, we were highly encouraged by the preliminary data presented from the endometrial cancer cohort of Part 2 of the ongoing paclitaxel study, which showed an objective response rate of 39% and a clinical benefit rate of 72% at eight weeks.

As we announced during our earnings call last quarter, we have also observed more than four responses in the ovarian cancer cohort, which has now advanced to the second stage of the Simon two-stage design. We look forward to presenting data in a poster presentation from the ovarian cancer cohort from Part 2 of the study at the ESMO Virtual Congress in September.

In addition, we announced today that we will be presenting data from Part 1 of the study of rebastinib in combination with carboplatin at the ESMO Virtual Congress.

We are also happy to confirm that we are on track to file an IND for DCC-3116, our potential first-in-class autophagy inhibitor designed to treat mutant RAS cancers, in the fourth quarter of this year.

Finally, I wanted to say a few words on the ongoing COVID-19 pandemic. Our studies remain open for enrollment and patients continue to receive investigational drug as well as appropriate follow-up. We are committed to supporting our clinical study sites and contract research organizations to help ensure patients receive care in a safe manner consistent with regulatory guidance.

I will now turn the call over to Tucker Kelly, our Chief Financial Officer, to review the financial results. Tucker?

Tucker Kelly, Chief Financial Officer

Thanks Matt,

I'd like to review the highlights from our second quarter financial results, which includes our first partial quarter of QINLOCK product sales. Total net revenues for the second quarter of 2020 was $7.1 million, which includes $4.8 million of net product sales of QINLOCK and $2.3 million of collaboration revenue. We recognize product revenue upon delivery of QINLOCK to our specialty pharmacy and distribution partners and the second quarter revenue includes net product sales from our first shipments in May following FDA approval. The gross-to-net adjustment in Q2 was slightly lower than our prior guidance. Please keep in mind that gross-to-net can vary quarter-to-quarter and we continue to expect the rate to be approximately 15% going forward.

In addition, we recognized $2.3 million in collaboration revenue under our agreement with Zai Lab, including a $2 million milestone payment due upon their submission of a New Drug Application to the China National Medical Products Administration for ripretinib for the treatment of adult patients with advanced gastrointestinal stromal tumor.

Cost of sales for the three months ended June 30, 2020, was immaterial, as the majority of the manufacturing costs related to second quarter QINLOCK sales were incurred prior to FDA approval, and thus, were recorded as R&D expense. Cost of sales will not be significant until the initial pre-launch inventory is depleted, and additional inventory is manufactured and sold.

In the second quarter of 2020 our total operating expenses, excluding cost of sales, were $76.0 million, which remained consistent with expenses of $75.3 million in the first quarter of 2020, as we support our commercial launch of QINLOCK as well as advance the clinical development activities across the pipeline. Research and development expenses were approximately $46.1 million and selling, general, and administrative expenses were approximately $29.9 million for the second quarter of 2020.

We expect our operating expenses will increase in the second half of the year compared to the first half of this year as we continue to support clinical development of our pipeline and the commercial launch of QINLOCK.

We ended the second quarter in a strong financial position and remain well capitalized to execute on the launch of QINLOCK in the U.S. and fund the development of our exciting pipeline of novel switch control inhibitors. We ended the second quarter with cash, cash equivalents and marketable securities of approximately $632 million, which we expect will be sufficient to fund our operations into the second half of 2022.

With that, I'll now turn the call back over to Steve.

Steve Hoerter, President & CEO – *closing remarks*

Thank you, Tucker.

Before we open the call for Q&A, I'd like to take a moment and thank the entire team here at Deciphera for their impressive focus and hard work over this past quarter. Looking forward, I am confident we are well-positioned to continue to execute successfully both on our QINLOCK commercial launch, building on the momentum of our first partial quarter of launch that we reported today, and our remaining promising development programs.

With that, Operator, I'd like to open the call for questions.