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PRESENTATION

Operator

Good morning, ladies and gentlemen. Thank you for standing by, and welcome to UroGen Pharma's Fourth Quarter and Full Year 2019 Financial Results and Business Update Conference Call. It is now my pleasure to turn the call over to Kate Bechtold, Senior Director of Investor Relations for UroGen Pharma. Please go ahead.

Catherine Bechtold - *UroGen Pharma Ltd. - Director of Corporate Communications & IR*

Thank you, operator. Good morning, everyone, and welcome to UroGen Pharma's Fourth Quarter and Full Year 2019 Financial Results and Business Update Conference Call. Earlier this morning, we issued a press release providing an overview of our recent corporate highlights and financial results for the quarter and year ended December 31, 2019. The press release can be accessed on the Investors portion of our website at investors.urogen.com.

Joining me on the call today are Liz Barrett, President and Chief Executive Officer; Dr. Mark Schoenberg, Chief Medical Officer; and Peter Pfreundschuh, Chief Financial Officer. Joining us for the Q&A portion of this call will be Stephen Mullennix, Chief Operating Officer; and Jeff Bova, Senior Vice President of Commercial.

Liz will provide a summary of our recent corporate developments, and Mark will share clinical development and regulatory updates. Peter will then provide an overview of our financial highlights for the fourth quarter and full year before we open up the call for questions.

As a reminder, during today's call, we will be making certain forward-looking statements. Various remarks that we make during this call about the company's future expectations, plans and prospects constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors, including those discussed in the Risk Factors section of UroGen Pharma's annual report on Form 10-K filed with the SEC this morning and other filings that UroGen Pharma makes with the SEC from time to time.

We encourage all investors to read the company's annual report on Form 10-K and the company's other SEC filings. These documents are available under the SEC Filings section of the Investors page of UroGen's website at investors.urogen.com.

In addition, all information we provide on this conference call represents our views only as of today and should not be relied upon as representing our views as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to update any forward-looking statements we may make on this call on account of new information, future events or otherwise.

I will now turn the call over to Liz.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Thank you, Kate. Good morning, everyone, and thank you for joining us today. I held my first quarterly conference call as CEO of UroGen this time last year, and I've had the opportunity to reflect on the tremendous progress we've made in 2019.

2019 was a pivotal year for the company, and our team over-delivered on the commitments and goals that we set out to achieve. We believe that our accomplishments in 2019 have set us up for the most transformative year in the company's history. This is the culmination of many years of work and dedication by the colleagues of UroGen Pharma. We are preparing to bring the first nonsurgical treatment option for low-grade upper tract urothelial cancer to patients who are in critical need of a better option.

Our top priority in 2019 was to complete the submission of the rolling new drug application or NDA to the U.S. Food and Drug Administration for UGN-101 for the treatment of patients with low-grade UTUC. At the end of last year, we were pleased to announce that the FDA accepted for filing and granted priority review for our NDA. The priority review designation shortens the review time from the standard 10 months to 6 months from the submission of the NDA. Our Prescription Drug User Fee Act, or PDUFA, goal date of April 18 is quickly approaching. As a reminder, the FDA previously granted Orphan Drug, Fast Track and Breakthrough designations for UGN-101 for the treatment of low-grade UTUC, reflecting the high unmet need in this area. We are very pleased with our discussions with the FDA and their willingness to partner with us to advance this innovative therapy.

We remain excited by their complete response rate, and importantly, the strong 6 and 12-month durability presented to date, and we expect publication of the final UGN-101 data in a prestigious journal, the first half of the year.

As you can imagine, we are intensely focused on the successful launch of UGN-101, as we await our potential approval. We are well prepared for commercialization in the United States with all commercial and medical colleagues in place. We've hired an outstanding team with deep experience in oncology and uro-oncology, led by Jeff Bova. The team is well into training and in the field, meeting customers and discussing their high unmet need and low-grade UTUC.

We employed a very efficient account-based approach with a nimble sales force of 48 representatives who will be able to reach 90% of the patient population. We believe that force will be able to swiftly and effectively reach our target urology practices.

In addition to the sales reps, we have a small team of 7 regional business managers, 7 clinical nurse educators to provide training and support around installation, and 7 reimbursement -- field reimbursement managers to ensure access and reimbursement.

In addition, earlier in 2019, we hired a team of 7 MSLs who have appropriately engaged with physicians interested in learning more about UroGen and our technology. Through our commercial planning process, we identified 3 key factors for a successful launch: patient identification, reimbursement and seamless integration into the physician practice.

First, low-grade UTUC is an orphan indication with approximately 6,000 to 7,000 eligible patients, and we will work closely with the nurse navigators in the practices to identify these patients upon diagnosis.

Second, because this is a buy-and-bill drug, physicians want confidence that they will get reimbursed before they will widely adopt. We have a comprehensive program in place to assist physicians in securing reimbursement. And our field reimbursement managers will be on-site to ensure that it's done correctly the first time.

In addition to our field team, we have secured the services of an experienced HUB to assist offices with all reimbursement and access questions. So patients in need of UGN-101 will be able to access it.

Notably, as CMS has moved from annual notifications of J-codes to quarterly notifications, we are optimistic that we will have a J-code by year-end. More importantly, physicians can also use a C-code, which we expect to secure by October of this year. Many of these procedures will be performed in a surgical center or a hospital where a C-code is necessary.

And the third key element in a -- is a seamless integration into physician practices. We want to make UGN-101 preparation and administration convenient for practitioners. We have several programs in place to support this, including our recently executed agreement with a national pharmacy partner to provide prepared admixture to urology clinics.

Our drug needs to be reconstituted with our gel prior to installation. While some offices and hospitals can do this themselves with the right equipment, most practices prefer to have it ready to use. Our pharmacy partner will deliver to the surgery center or the hospital, ready for installation. All logistics will be coordinated through our support HUB for a seamless customer experience.

Increasing awareness of UGN-101 and UroGen is a critical component of adoption and was a key initiative over this past year.

In 2018, only about 30% of physicians were even aware of UroGen and UGN-101. As of AUA, this past year, it was up to 70%, and we expect it to be even greater by launch. We know from our recent market research that 88% of urologists desire a new and differentiated treatment option for their patients. The results of this research support our belief that, if approved, this will be a typical adoption curve and used across the treatment continuum in newly diagnosed patients and recurrent patients as well as those with resectable and unresectable disease.

Urologists recognized the need to delay radical surgery, and we are very encouraged that there will be multiple opportunities to incorporate UGN-101 into their physician treatment options of low-grade UTUC, following anticipated FDA approval.

Our teams are excited and fully prepared to bring UGN-101 to patients who have been waiting. Beyond anticipated launch in the U.S., we are progressing research to identify opportunities to bring UGN-101 to patients in other parts of the world. We also continue to advance our leading pipeline of uro-oncology candidates. We are accelerating development of our next candidate, UGN-102, for the treatment of patients with low-grade intermediate risk non-muscle invasive bladder cancer.

Similar to UGN-101, with UGN-102, we are seeking to address the high unmet need and improve the standard of care for patients who deserve better options. Currently, there are no drugs approved for the first-line treatment of low-grade non-muscle invasive bladder cancer. In the current standard of care, transurethral resection of bladder tumor, or TURBT is used repeatedly to address chronic recurrence of disease.

The specific patient population of low-grade patients we are targeting are patients classified as intermediate risk and have a particularly high rate of recurrence. These patients could be considered surgical failures. We believe UGN-102 has the potential to provide a nonsurgical alternative for the treatment of approximately 80,000 patients in need of new treatment options.

We were pleased to share positive complete response data from an interim analysis of over half of the patients from the Phase IIb OPTIMA II study last year, and intend to report durability data, including 12-month durability in a cohort of patients in the first half of this year.

We are in ongoing discussions with the FDA and experts in the field to finalize the design of our pivotal Phase III study that will be compelling from a regulatory and clinical perspective, and give us the quickest path to bringing this important medicine to patients. We remain on track to initiate the study this year.

We believe that the peak revenue potential of UGN-101 and UGN-102 could be greater than $1 billion, providing a strong foundation from which to build a long-term sustainable growth business.

Beyond low-grade disease, we're excited about advancing UGN-302 for high-grade non-muscle invasive bladder cancer. Mark will provide further details, but UGN-302 is a combination of UGN-201, our TLR7/8 agonist with zalifrelimab and anti-CTLA-4 antibody we licensed from Agenus. The initial indication is supported by the encouraging nonclinical work we previously shared. We continue to explore other areas for both local delivery and novel medicines in adjacent spaces, further building upon our leadership position in urology and specialty cancers.

With that, I'll turn the call over to Mark to discuss our clinical development programs and progress in more detail. Mark?

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Thank you, Liz. This past year has been very eventful for UroGen. Our proprietary RTGel provides an innovative platform for developing nonsurgical therapies that can be applied to diseases traditionally treated by surgery such as low-grade UTUC and bladder cancer.

As we await potential approval of our first medicine, UGN-101, we remain encouraged by the complete response and durability data previously presented.

As a reminder, the final analysis of the primary endpoint of our pivotal Phase III OLYMPUS trial demonstrated a 59% complete response rate in patients with low-grade UTUC. Durability of response was estimated by Kaplan-Meier to be 89% at 6 months and 84% at 12 months after primary disease evaluation. The estimated median time to recurrence was 13 months, and 34 of the 71 patients treated in the study were initially characterized by the treating physician as having endoscopically unresectable tumors. These are the patients who, according to the current standard of care, would be candidates for immediate kidney removal.

The most common treatment-emergent adverse events included ureteral stenosis, urinary tract infection, hematuria, flank pain, nausea, dysuria, renal impairment and vomiting. The majority of these were characterized as mild to moderate in severity and transient. These adverse events are familiar to urologists, given the disease being treated and the instruments utilized. As Liz stated, we are eagerly anticipating publication of the final results of the primary endpoint from the OLYMPUS trial in the near future.

Similar to low-grade UTUC, low-grade intermediate risk non-muscle invasive bladder cancer remains a challenge to urologists, given the frequent rate of recurrence that has been difficult to control using standard of care surgical intervention or TURBT. The intermediate risk population is an emerging clinical entity, defined by 2 or more of the following characteristics: multifocality, tumors greater than 3 centimeters and rapid rates of recurrence.

In September, we presented complete response data from an interim analysis of the Phase IIb OPTIMA II study of UGN-102 in patients with low-grade intermediate risk, NMIBC. In this cohort of 32 patients, 20 patients or 63% achieved a complete response. In interim analysis, there were no serious adverse events reported. The most common treatment-emergent adverse events observed were dysuria, frequency of urination, fatigue, hematuria and urinary tract infection. We look forward to sharing updated complete response and durability findings from this study in the next few months. These findings, coupled with positive results from the OLYMPUS study, further support our excitement about advancing UGN-102 in patients with low-grade intermediate risk non-muscle massive bladder cancer.

From both a clinical and molecular perspective, low-grade UTUC is very similar to low-grade NMIBC. We are optimistic about the potential of UGN-102 to have an immediate impact and provide approximately 80,000 intermediate risk patients with a nonsurgical option for the treatment of chronic relapse.

As Liz mentioned, we are actively engaged in discussions with the FDA to finalize the design of our pivotal Phase III protocol and expect to begin the study in the second half of the year. We look forward to updating you on the trial design once finalized.

While our lead programs are focused on low-grade disease, high-grade NMIBC remains a significant clinical challenge for patients and physicians. Even as we have seen, new medicines approved recently for these patients, the benefit remains limited and new options are needed. Patients with high-grade disease who fail conservative therapy may require bladder removal surgery or radical cystectomy. This procedure is associated with significant morbidity in an elderly population.

Based on encouraging nonclinical data we shared in September, we believe UGN-302, a combination of UGN-201 with zalifrelimab, may provide a therapeutic alternative to cystectomy for patients who fail standard of care treatment with agents such as BCG.

We are continuing formulation in nonclinical development in advance of initiating human studies later this year. We will provide details on the program at a later date.

And with that, I would like to turn the call over to Peter, who will discuss financials.

Peter P. Pfreundschuh - *UroGen Pharma Ltd. - CFO & Secretary*

Thank you, Mark, and good morning to everyone on today's call. UroGen is well capitalized as we prepare for potential U.S. approval and launch of UGN-101, and advance our clinical development programs, including initiation of UGN-102 Phase III trial later this year.

We closed the fourth quarter of 2019 with $195.6 million in cash, cash equivalents and marketable securities, this excludes restricted cash.

For the fourth quarter and full year ended December 31, 2019, we reported net losses of $39 million or $1.86 per share, and $105.1 million or $5.12 per share, respectively. This compares to net losses of approximately $23.7 million or $1.46 per share, ,and $75.7 million or $4.80 per share for the same period in 2018.

The net losses for the fourth quarter and full year ended December 31, 2019, include $8.1 million and $30 million, respectively, in non-cash stock-based compensation expense.

Research and development expenses for the fourth quarter and full year ended December 31, 2019, were $20.1 million and $49.3 million, respectively, compared to $11.5 million and $36.9 million for the same periods in 2018. Research and development expenses include $1.9 million and $8.3 million of noncash stock-based compensation expenses for the fourth quarter and full year ended December 31, 2019, respectively, as compared to $3 million and $12 million for the same periods in 2018.

Setting aside noncash stock-based compensation expense, the year-on-year increase from 2018 to 2019 was mainly attributable to costs associated with milestone payments related to our licensing agreement with the Agenus Inc., the purchase of API and other manufacturing activities as we prepare for our UGN-101 product commercial launch, increased clinical activities for UGN-102 Phase IIb clinical trial, and an increase of headcount and the related costs supporting increased clinical trial activities.

General and administrative expenses for the fourth quarter and full year ended December 31, 2019, were $19.7 million and $60.2 million, respectively, as compared to $12.6 million and $39.6 million for the same period in 2018.

General and administrative expenses include $6.2 million and $21.7 million of noncash stock-based compensation expense for the fourth quarter and full year ended December 31, 2019, respectively, as compared to $5.9 million and $18.6 million for the same periods in 2018.

The increase from 2018 to 2019 was mainly attributable to the increase in headcount and related costs as part of the build-out of our company in anticipation of commercialization of our first product, commercial services, consulting and other outside fees as well as noncash stock-based compensation expense.

As of December 31, 2019, we had approximately 21 million ordinary shares outstanding. Based on our current plans, we are well capitalized for a strong commercial launch and continued advancement of our pipeline. The company anticipates operating expenses for 2020 in a range of $145

million to $155 million. The increase in operating expenses in 2020 is largely attributable to having a full commercial organization in place for the whole year.

Noncash stock-based compensation expense for 2020 is expected to be in a range of $32 million to $36 million, subject to market conditions, and other nonoperating income for 2020 is anticipated to be approximately $2.5 million, subject to market conditions.

With that, operator, I would like to turn the call over for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from Derek Archila from Stifel.

Derek Christian Archila - *Stifel, Nicolaus & Company, Incorporated, Research Division - Director & Senior Analyst*

Just a few from us. Just first on the reimbursement, can you just give us a sense, so you said that you -- and likely would have a J-code by the end of this year, even when they're doing the quarterly review. So I guess, why could we see potentially a J-code by like the end of September, maybe just kind of walk us through the timing on that? And then the other component. Have you guys done any additional research in terms of the overall cost of UTUC patients in terms of kind of health care economic data? And that those are the things.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Derek, it's Liz. I'll answer the question on the cost, and then turn it over to Jeff. He can give you more specifics about the reason why we stay -- you're right, we could get -- potentially get it earlier, but they have very specific dates. I'll let Jeff give you the details on that. We actually have tried to do a lot of work around the cost. But to be honest with you, have not been very successful because the issue with these patients after kidney removal is really the cost of managing these patients over time. And there's not great data about the long-term management of these patients. So we do have some health economic data, but not a lot of health economic data. We know, and obviously, Mark can talk to you more about the sequela associated with the kidney removal in these patients and some of the things that they -- that impact their lives. I'll let Mark just sort of briefly talk to you more qualitatively about that. And then, Jeff, if you could answer the question more specifically on reimbursement, that would be great. So Mark?

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Derek, the sort of the short story on the downstream effects of kidney removal is that we know, and there's actually recent peer review literature on this, the patients who undergo kidney removal, who are elderly and, therefore, have other comorbidities, have an increased risk, not only of chronic renal insufficiency, obviously, but also the downstream effect of this, one of the most important of which is the exacerbation of cardiac disease. So we do know that in the elderly population, and that is the population we're talking about with respect to the treatment of this disease, that kidney rural is not a benign procedure and does have downstream effects that are costly to the system, probably the most important of which is exacerbation of other comorbidities.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes. And I think that we've talked a lot about the fact that on a per patient basis, being the most costly cancer and it's associated with the fact of the kidney removal and managing these patients over time, but unfortunately, the specifics around that aren't really readily available. So Mark -- Jeff, can you just talk more specifically about the reimbursement and our comment on J-code?

Jeffrey Bova - *UroGen Pharma Ltd. - SVP of Commercial*

Sure. Thanks. And thanks, Eric, for the question. It all depends on timing from an approval standpoint. Yes, you're correct, CMS has moved to a quarterly approval, so it is possible that we could have a permanent J-code, October 1. Liz also mentioned the importance of a C-code. A C-Code is a unique pass-through code that CMS could grant us as early as October as well. So in short, it depends on the timing of approval. Once approved, we're ready to submit for both cards -- codes.

Operator

Our next question comes from Chris Howerton from Jefferies.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

So I guess, Derek obviously asked on the launch. Is there -- how -- with respect to the coding and the reimbursements moving forward, how should we expect gross to nets to evolve over at least this first year and moving forward from there with respect to those codings? And then I have a follow-up question on the pipeline.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes, it's -- there's not really -- there's not a lot of need for discounting in this space. So the gross to net from that perspective, it really doesn't -- the codes don't really impact the gross to net as much, right? So while we're not guiding specifically on what the gross to net is, I would say it's fairly typical, but not on the high end, where you would see most of -- some of these therapies that get -- that are high competition, right at the 20% type of discount. We don't -- we won't really see a need or have a need to be discounting with payers. That's really where you see our gross-to-net erosion. So again, you'll see your typical percentages from administration and those types of gross to net. But that's sort of what we can say about gross to net. I don't think you'll see a very high gross to net, considering that we're the only nonsurgical treatment. So we won't be competing competing against others in this space and needing to discount.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

Okay. And then, I guess, for -- I suppose this would be for Mark or whoever on the team. But with respect to 102 and the potential pivotal design here, what are the key features that you hope to get in an alignment with regulators? Is it trial size? Is it endpoint? What are the kind of key sticking points? And then as a corollary to that discussion, has there been any involvement in terms of the discussion with respect to chemoablative therapy versus an adjuvant to TURBT because we're still getting questions, at least on the buy side with -- on that point, so if you could address both of those, that would be great.

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Thanks, Chris. Let me take the first one -- no, rather the second one first. So this is not an adjuvant therapy, this is a primary chemoablative therapy. And we're committed to that for reasons that I think everybody on the call understands, but let me just reiterate them. The value to patients and the physicians of a primary chemoablative approach to this disease is that it can be performed without anesthesia in the office. And that is a great benefit to patients who have a multifocal disease, who could, therefore, not only have their disease addressed, but have it addressed without the need for anesthesia, which is an important component of the overall care of elderly patients. With respect to the design, we are working closely with the FDA, the issues of trial design here revolve around size, you're right power to make sure that we are appropriately powering to show the types of differences between groups that we aspire to. And I think we're in pretty good alignment. It's just a matter of deciding some very specific questions around control group design and characterization that we're finalizing, and we hope to share that with you soon.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes. And just to add to that, on the -- when you think about the reason why chemoablative versus adjuvant therapy is because we -- these patients are patients who actually surgery hasn't worked. And we hope to -- that they'll avoid having to get another TURBT. So -- and then Mark has talked many times about the reason why you really can't go in right after TURBT and give mitomycin from the perspective of the side effects of mitomycin in an area where you just had surgery. So I think all those reasons, the best benefit to these patients is that they'll actually avoid the TURBT. And then in the data we shared, we have a very high CR in those patients, and we're waiting on durability data, but the durability data plays out. Then these patients that typically go in potentially several times a year would not have to go in and have TURBT. So -- but thanks for the question.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

Sure. And if I can sneak in just maybe one more with respect to 201 in the high-grade. Obviously, we've had a recent approval, maybe not in this particular setting that you're going after, but similar for Keytruda. So just curious how you think this positioning for 201 will look like when you do enter the clinic and for the eventual approval?

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

It's a great question. And I think one of the things to keep in mind about the recent approval of Keytruda is, it's an approval of a systemically administered drug for an extended period of time. And we are currently approaching the formulation of 301, which is this combination therapy as an intravesical approach to the management of refractory or high-grade noninvasive disease. That's a format that would permit urologists to treat patients in a very familiar way in the office, which is what's done now. So I personally believe that this would be a completely differentiated approach compared to the Keytruda approval. And I don't think it represents a disadvantage at all, in fact, I think it represents an advantage.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

I think the other thing to keep in mind, Chris, is the response rate that they're seeing, right? I mean, look, we're really happy, frankly. I think it's great for patients that all of these products are being approved. But you have to look at their data, they're getting approved on just a small percentage of the patients actually being -- getting a good response. So I think that there's still a very high unmet need in this post-BCG, and then hopefully, eventually, being able to replace BCG. So I think it's still a high unmet need in that patient population. And I think you see that by the number of molecules out there that are being studied in this area.

Christopher Lawrence Howerton - *Jefferies LLC, Research Division - Equity Analyst*

Right. Well, yes, so point taken in terms of the intravascular delivery. And then, of course, also, those patients were ineligible for sicectomy or chose not to take it. So bit of a skewed results for sure.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

No, yes. Yes, sure, absolutely. And as Mark stated, the -- being able to give local delivery versus having the side effects associated with treatments like the PD-1 inhibitors. I think what we believe is that being able to give a CTLA-4, that has the benefit of a checkpoint inhibitor without the side effects. So thanks a lot, Chris.

Operator

Our next question comes from Paul Choi from Goldman Sachs.

Kyuwon Choi - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

I wanted to follow-up with regard to another question on 102. And just maybe ask Mark and the team, how you're thinking about any observations or learnings from the interim data that you've presented earlier with regard to refining patient selection or thinking about any additional inclusion or exclusion criterias, just to boost your probability of success here? And then just how you're thinking about how we should, with regard to the control arm, think about the response rates relative to what's established in the literature? And then I had a financial question as a follow-up.

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Thank you, Paul. So I think, happily, the design of our ongoing IIb trial has helped us really understand that we picked the right group at the outset of that trial. So we are focused on a group that we've characterized based on both AUA and other professional organization criteria, as comporting with definition of intermediate risk disease. This is the population that has chronic recurrence. As Liz mentioned earlier, frequent surgical intervention with all of the attendant disadvantages of that approach. So we believe that the population we're currently studying actually does represent the right population, both based on definitions and also based on our current data, which we've shared with you. So I think the population is what it is. And just to answer the question about the performance of the control group, which would be, of course, how these patients do with a contemporary standard of care, which is transurethral resection of bladder tumor, we know that this population is the group of people who have recurrent disease on multiple occasions after transurethral. So as Liz has said many times, this is the group of people you could characterize as surgical failures. So we're expecting recurrence rates in that arm to be anywhere from 60% to 80% based on what we've understood from the peer review literature. Obviously, the trial would have to play out. But I hope that kind of level sets for you what our expectations are with regard to -- with respect to the control group performance.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes. And just to reiterate, Paul, I think, as Mark said, we did do it right. And I think the patient population we're looking at -- in 102 is exactly the same patient population, which is great for us because it also makes it easy when we launched the study to be able to start in those hospitals and institutions where we currently are running 102. And you said you had a financial question?

Kyuwon Choi - *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Yes. Just as a follow-up, just a quick one for Peter. Just want to double check to see if you had, with regard to the upcoming launch, any R&D inventory that will bleed off before you transition to a regular COGS over the course of 2020?

Peter P. Pfreundschuh - *UroGen Pharma Ltd. - CFO & Secretary*

Good question, Paul. And as a matter of fact, if you go through our script that we went through with you guys on today's call, we did reference the fact in our R&D expense that we actually had prebuild of API as well as other related costs associated with the build of inventory in advance of the commercial launch of UGN-101. So in fiscal 2019, those costs were actually embedded in research and development expenses. We did not call out specifically how much, but good question because we will bleed that off and that was expensed in 2019. It will also be expense leading up to the actual approval. And upon the approval, we'll flip to capitalizing any further build of inventory and run it through our P&L appropriately. So what you will see is, for at least the initial period of launch, cost of goods will be skewed, favorable relative to the prebuild of inventory, which actually will not run through the P&L.

Operator

Our next question comes from Ram Selvaraju from H.C. Wainwright.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

A couple of quick ones first. Could you comment on the nature of the 3PL organization? And maybe describe for us the process workflow from the point of prescription entry to the point of prescription filling and administration of the drug? And if you could give us a sense as to whether from a distribution channel perspective, this is similar in concept to a specialty pharma network? And then also with respect to the sales force composition and prior history and performance of the sales folks that you have on board, if you could maybe give us some background on the kinds of drugs that they've been promoting in the past? Kind of what their performance history was with those drugs, to whatever extent you're able to disclose that?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes, sure. And I'll just let Jeff answer that. But I just want to congratulate Jeff, frankly, on the -- his ability to attract some great sales representatives and colleagues to the company. I can say we had no shortage of people interested in joining, and I think that, that's also a testament to where we're headed. So Jeff, can you answer more specifically, the questions around the 3PL and the distribution channel as well as give him some more guidance around where the sales force came from? I know it was many different companies, but I think it would be helpful to share that additional context.

Jeffrey Bova - *UroGen Pharma Ltd. - SVP of Commercial*

Sure. And thanks, Rob. The -- you're correct. The orders will go through a 3PL. The actual order itself will come in through the HUB. So if -- when a physician is -- wants to administer this to a patient, there'll be an 800 number that they call that will go to our HUB. That HUB will then process the script similar to other drugs that are in this space, like a Provenge or Radium-223. The 3PL then will ship product to the specialty distributor, and the distributor will then ship product to the hospital or the surgery center. So yes, if the 3PL is where it starts, we will have a specialty distributor as well, which is different than drugs that are specialty pharmacy, those are particularly Part B. Since we're a Part B drug, we will go through the specialty distributor. With regards to the field force, yes, we were able to get a lot of talented folks from those that are in the urology space. Our field force has an average of about 10 years in the genitourinary space. They don't come from any one company in particular. They come from a variety of companies in the space that have a significant amount of experience selling drugs in anything from hormone-sensitive prostate cancer to castrate-resistant prostate cancer that -- or some sort of urology drugs experience. So hopefully, that helps.

Raghuram Selvaraju - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Absolutely. And then a couple of additional ones. Just wanted to clarify. Are you expecting to be able to start booking sales of 101 in 2Q 2020? Or is that still kind of open as to whether that would definitely occur? And then can you perhaps, maybe this is a question for Peter, give us some sense of when you might be in a position to give revenue as well as OpEx guidance? And whether this might occur later this year or perhaps next year? And finally, with regard to the clinical development plan for UGN-302, I wanted to see if any combo trials are likely to start before the end of this year? Or if we should expect that later? And also, if you could maybe comment, I don't know if you're in a position to do this, but give us a sense of whether we should see any additional clinical readout information on BotuGel before the end of this year as well?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes, I'll answer the last 2 and then turn it over to Peter too. But I would not expect that we'll see studies in the combination this year. I think we will be in human studies this year, but we'll be working through through dose escalation and dose optimization. On the BOTOX Allergan collaboration. If you look at ClinicalTrials.gov, you do see that their primary completion date is in the May time frame. And so we would expect a few months after that, that they'll have data. Now what they decide to disclose will obviously be up to them as their decision is from a materiality's perspective. But we do expect that by the end of the year, we will have a path forward and be able to share at least some information on where we're headed with that. ElAnd with that, I'll turn it over to Peter, and he can answer your first couple of questions.

Peter P. Pfreundschuh - *UroGen Pharma Ltd. - CFO & Secretary*

So I'll answer the revenue guidance question first, and then we'll kind of back into 2020 and sales, which I know you asked about. So first off, as you saw through our earnings release here, we did provide guidance with regards to operating expense, share-based compensation and nonoperating income. We did not provide guidance with regards to revenue or bottom line net income. If you look typically speaking, 8 out of 10 biotech companies out of the gate usually do not provide revenue guidance. I think we're following that paradigm. The 2 or 3 that do, call it, 2 out of 10 you see that typically speaking, when they do do that, they, for various reasons, don't get it always right. So we think that the prudent approach is not to provide revenue guidance, and obviously, not to provide bottom line net income or cash flow guidance relative to 2020. You guys are smart. You'll back into those numbers if we provide one or the other, so to speak. I think from our perspective, we've gone around the street, had a lot of discussions with yourself as well as many of your colleagues, the other analysts that are on the line. I think over the course of time, we've had those conversations. I think, where the consensus numbers are right now, they're relatively in line. Kind of with the conversations that we've had, we point to various numbers that are out there. So again, we're not going to provide specific guidance per se for this year, and I think look to the consensus number that's out there as kind of the guidance per se. With regards to booking revenue for this year, the guidance that we have provided to yourself as well as the Street is that you can expect that we'll book revenue for Q3 and Q4 this year. Should we have the opportunity to book revenue in Q2 because of earlier timing? We'll do that. But again, our guidance to the Street is, presumed it's a Q3, Q4 event.

Operator

Our next question comes from Matt Kaplan from Ladenburg Thalmann.

Matthew Lee Kaplan - *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

I guess, maybe a question for Liz or Jeff. Can you provide us some more color or describe in more detail the, I guess, initiative in terms of the solutions around the patient ID program, the reimbursement program to, I guess, really drive uptake of 101 as you launch it following approval?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes, sure. Jeff, why don't you take the question?

Jeffrey Bova - *UroGen Pharma Ltd. - SVP of Commercial*

Sure. Thanks, Matt. Liz had mentioned earlier, the importance of the relationship with the nurse navigator in the practice. So what we've done is hired folks to have that experience, that relationship because, as you pointed out, it will be important to identify those patients that are eligible for UGN-101. So that's certainly in place. The other thing that we have is there is a company that works mainly with urology accounts that helps identify those patients, it's an EMR company that will help identify patients that are obviously eligible. So we'll work with them to help sort of have a rapid alert for if those patients do come in and they're diagnosed, either initially with low-grade UTUC or if there are recurrent patients. So that will help as well. With regards to reimbursement, we do have a very experienced field reimbursement team in place to help with the coding and billing that will take place upon approval. The field reimbursement team will sit down with reimbursement managers in practice or the hospital to make sure that the forms are being filled out correctly to incur accurate and timely reimbursement.

Matthew Lee Kaplan - *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

Okay. That's helpful. And then just shifting gears in terms of your pipeline. I guess, a question for Mark. For 102, I guess, where do you think it will fit into the current treatment paradigm for low-grade, I guess, intermediate risk non-muscle invasive bladder cancer?

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Yes. So the problem with these patients is that they get chronic surgery. And that is a tough way to treat an elderly population. I actually think that, and I know this personally from my own practice and I know this talking to my colleagues, these patients are difficult to care for, and it's debilitating both for physicians from a psychological perspective and also for patients physically to constantly rotate through what appears to become a sort of futile exercise in managing a chronic illness. So I think that 102 represents a different way of thinking about the disease. It is, from a scientific perspective, more sophisticated because it treats the entire field of disease, which we do know is expressed in this population. These are patients who have multi-focal recurrent cancers. And you can't really approach that surgically and the contemporary results, I think, underscore that. So not only do I think it's going to be applicable to the care of the population, but I think it's going to be applicable to the majority of these individuals because physicians readily appreciate that we're really not doing a good job caring for these people, and we need a better alternative. And I think 102 is that better alternative.

Matthew Lee Kaplan - *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

Great. So this -- in other words, this will be used in lieu of surgery because these patients really aren't eligible for it as...

Mark P. Schoenberg - *UroGen Pharma Ltd. - Chief Medical Officer*

Yes, I mean, I would imagine that, that -- I mean, again, this is speculative on my part, but I would imagine this will appear to be a very appealing alternative to patients and physicians once it's available. Because it really is more rational in terms of how we know the disease evolves.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

And Matt, just -- it's Liz, just to sort of add some more context around that. When you think about the patient population, the low-grade non-muscle invasive bladder patient population, the prevalent pool is the majority of the patients, right? So you have your incident pool of patients that come in that you can recognize, as Mark's talked about, through the different factors that would specify a patient to be this low-grade intermediate risk patient. But importantly, I think a big driver of that is what -- I mean, you've heard us talk, and particularly, Mark talked a lot about, those patients that just continue to come in, they're very -- these physicians are very frustrated because they don't have a way to treat those patients. And actually, that's about 80% of the patient population in our total pool. About 20% of the annual patient population will be the new patients and newly diagnosed patients. So I think we feel like we have a great alternative to those patients who have already seen TURBT several times and clearly it doesn't work for them, and then as physicians begin to recognize that patient when they come in, more likely, they'll want to try to treat with 102 first, and see if they can get a response with 102 before going through -- going to a TURBT. So I think it's important just to understand that this, the patient population is -- so it's a patient population that lives for many, many years with low-grade non-muscle invasive bladder cancer.

Matthew Lee Kaplan - *Ladenburg Thalmann & Co. Inc., Research Division - MD & Head of Healthcare Equity Research*

Okay. Yes, that's very helpful. And then last question in terms of -- can you give us a little bit more color in terms of the role of the national pharmacy partner? Are they going to be preparing the -- this year, of 101 for use in all clinics? Or how are they going to -- how is that going to work?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Yes. I mean, it will actually be their choice, but we expect that the majority of physicians will want to use it. If they have the right equipment and in some hospitals, they may want to mix it themselves, and they'll be able to do that. But we expect the majority of the time and even physicians that actually have the ability to do it, they -- it takes a nursing time to mix, so we expect that most -- the majority of either even in the hospital into clinics where they have the surgery centers, wherever they are, that they'll want to use our mixing partner. So you're right in the sense that, basically what's going to happen is that the pharmacy will mix and get it to the physician at the time that they have their procedure scheduled. And Jeff and the team have a lot of experience, and his past experience was doing just this, and it really has worked extremely well. So we're very confident

that this is -- this will work in our advantage because as physicians have said, you don't want to make it easy for me, and this is exactly what we're doing.

Operator

Our next question comes from Maria Barbara from National Securities.

Maria Antonia Barbera - *National Securities Corporation, Research Division - Research Analyst*

The first question is regarding the ex-U. S. regulatory pathway and commercialization. And I was wondering if there have been any progress in terms of the conversations with regulators in Europe and Japan for UGN-101?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

We have not advanced that. To be honest with you, the regulatory team here has been knee-deep in with the FDA. So while we have had initial consultation with some consultants on the -- in Japan and in Europe, we actually want to -- we need to wait until our FDA approval in the U.S. before we take those resources and start to actually have meetings. But we've done a lot of the foundational work. And we -- I think we understand what would need to be done. But now it's just a matter of actually having the official and formal meetings with those regulatory authorities. As stated before, in the past, that in Europe, it's really not a regulator. We did have some regulatory interaction before, it's more of a payer interaction. And so we're really working on getting in to see the German authorities, and the Germany, France and the U.K., which are the big the big countries to understand what they would need to see to be able to ensure we can get a decent reimbursement and make it financially viable for us to even go into Europe, and that would be with 101. As we approach 102, we want to look at it and hopefully be able to design a study that would not only give us a regulatory approval in the U.S., but even in some other countries around the world as well. So we expect that to be a global study. So I hope that helps.

Maria Antonia Barbera - *National Securities Corporation, Research Division - Research Analyst*

Okay, great. And then staying with 101. I was wondering if you could share if any patients have been enrolled in the retreatment extension study?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Unfortunately, no. And actually, we'll have to look at an alternative alternative as we begin to launch for another retreatment study. I guess, the good news is, is that there haven't been a lot because there haven't been a lot of recurrences. So that's sort of a good news, bad news story, but more of a good news than anything. We also do believe in our conversations with physicians that there wouldn't be any reason that they wouldn't retreat. They've all said that they would retreat. But we do think it's important for us to gather data, assuming that they have the type of durability that we've seen in the study that they would retreat these patients. And we believe that, that would be viable and not an off-label use of our medicines. So we do want to continue to get and gather data on retreatment, but it looks like we'll have to maybe do a Phase IV study post-approval.

Maria Antonia Barbera - *National Securities Corporation, Research Division - Research Analyst*

Okay. And then regarding the medical science license. I think you said there are 7 of them, I'm assuming one per region. And I believe they have been out in the field since early 2019. And I was wondering, what is the feedback you get from the MSLs about the interactions with the physicians? And how have those conversations changed if in any way since early 2019 when they went out to the field to now early 2020, one year later?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Well, I think it's really important to keep in mind the role of an MSL, right? The role of an MSL is not a promotional role, it's really an educational role and to be able to have peer-to-peer conversations with physicians. So we don't track. It's not appropriate to track sort of promotional-type events with an MSL. So what I can tell you, though, and I'll turn it over to Jeff and let him talk to you about not the MSL specifically, but what progress we've made as a company and physicians, their perception and their awareness of UroGen in our products over the last year. So Jeff, I just want to talk about the most recent research that we received.

Jeffrey Bova - *UroGen Pharma Ltd. - SVP of Commercial*

Sure. So the MSLs have been, for the last year, a huge help with regards to a couple of factors. We've attended every urology conference that really is relevant to UGN-101, and they are able to have sort of a clinical discussion in around the data that's been published for 101. So there's a significant interest that we saw an increase in 2019 just from having a strong presence at these meetings. The research that Liz is alluding to is in around awareness. So over a year ago, our awareness was around 30 -- 40% for UGN-101 and for the company itself. Because of that presence that we've had and those discussions, the awareness is shot up to around 70%, 75%, so 3 quarters of the physicians are aware of 101. You can imagine when we have a booth at these congresses, there's a significant amount of questions, interest in and around the product. And then the question we have to get off is, are we approved or when we approved? I think physicians are -- have in their mind a specific number of patients that are waiting for approval. So that awareness is something that we can capture and we can measure, and the MSLs have done a great job out there raising that.

Maria Antonia Barbera - *National Securities Corporation, Research Division - Research Analyst*

Okay. And then lastly, in terms of pipeline. Is there any update on the formulation feasibility study that you were doing with Janssen?

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Not at this time, no.

Operator

I am showing no further questions at this time. I will now turn the call back over to UroGen's President and CEO, Liz Barrett, for closing remarks.

Elizabeth A. Barrett - *UroGen Pharma Ltd. - President, CEO & Director*

Thank you, operator. And I must say I'm incredibly proud of our team and all that we've accomplished in 2019. We put together a mission to pioneer new treatments to improve patient care in specialty cancers and neurologic diseases, and we're really advancing on that mission. We're excited about the many key events on the horizon, especially the potential approval of UGN-101. And I'm confident that given what we've demonstrated today that this is just the beginning of what UroGen will be able to achieve. So we really appreciate all of your interest and time this morning and your continued support. So operator, you can now disconnect. Thank you.

Operator

Thank you, ladies and gentlemen. This concludes today's conference. Thank you for participating, and you may now disconnect.
