UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of the earliest event reported): July 31, 2018

NEUROCRINE BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**0-22705**	**33-0525145**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12780 El Camino Real, San Diego, California	**92130**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 617-7600

N/A
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2 (b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4 (c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On July 31, 2018, Neurocrine Biosciences, Inc. (the "***Company***") held a live conference call and webcast to discuss, among other things, the Company's financial results for the second quarter ended June 30, 2018. A transcript of that conference call is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks are described more fully in the Company's filings with the Securities and Exchange Commission, including without limitation the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other documents subsequently filed with or furnished to the Securities and Exchange Commission. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

99.1 Transcript of the Neurocrine Biosciences, Inc. conference call on July 31, 2018.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: August 3, 2018

By: /s/ Darin M. Lippoldt
Darin M. Lippoldt
Chief Legal Officer

31-Jul-2018

Neurocrine Biosciences, Inc. (NBIX)

Q2 2018 Earnings Call

CORPORATE PARTICIPANTS

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

Jane Sorensen
Executive Assistant, Neurocrine Biosciences, Inc.

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

OTHER PARTICIPANTS

Geoff Meacham
Analyst, Barclays Capital, Inc.

Phil Nadeau
Analyst, Cowen & Co. LLC

Brian P. Skorney
Analyst, Robert W. Baird & Co., Inc.

Biren Amin
Analyst, Jefferies LLC

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch

Alan Carr
Analyst, Needham & Co. LLC

Anupam Rama
Analyst, JPMorgan Securities LLC

Sumant Kulkarni
Analyst, Canaccord Genuity, Inc.

Jay Olson
Analyst, Oppenheimer & Co., Inc.

David A. Amsellem
Analyst, Piper Jaffray & Co.

MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to Neurocrine Biosciences Reports Second Quarter 2018 Results. At this time, all participants are in a listen-only mode. Later, you will have the opportunity to ask questions during a Q&A session. [Operator Instructions] Please note today's call is being recorded and I will be standing by should you need any assistance.

It is now my pleasure to turn the conference over to Kevin Gorman, CEO. Please go ahead, sir.

Kevin Charles Gorman

Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

Thank you very much and welcome, everyone, to our quarterly conference call. Before we start, we're going to be making forward-looking statements. So, Jane, if you could read our Safe Harbor statement, please.

Jane Sorensen

Executive Assistant, Neurocrine Biosciences, Inc.

Okay. Certain statements made in the course of this conference call that are not historical statements may be forward-looking statements which are subject to risks and uncertainties. Information concerning factors that could cause actual results to differ materially from those contained in or implied by the forward-looking statements is contained in the company's SEC filings, including, but not limited to, the company's Quarterly Report on Form 10-Q filed today and in today's press release. Copies may be obtained by visiting the Investor Relations page on the company's website. Any forward-looking statements are made only as of today's date and we disclaim any obligation to update these forward-looking statements. Kevin?

Kevin Charles Gorman

Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

Thank you, Jane. So, I'm joined here today by Eiry Roberts, our Chief Medical Officer; Matt Abernethy, our Chief Financial Officer; and Eric Benevich, our Chief Commercial Officer.

I'd like to start the call off by congratulating our partner, AbbVie, and, in particular, the entire clinical and regulatory team in Chicago. They've done an outstanding job with elagolix since we formed this partnership several years ago. I think that I echo what Rick Gonzalez said on their call earlier in the week that the label for ORILISSA is an outstanding label. And it is indicative of, it's reflective of the real high quality Phase III program that was conducted by AbbVie.

We have flexibility of dosing in this label. There is no monitoring requirements in this label. While there is a recommended duration of dosage treatment, the patient can stay on the drug and definitely that is a decision up to the patient and their physician. There is no restriction on duration of dosing. There is no boxed warnings. And so I really think that this label is outstanding and, as I said, the quality of the development program, the regulatory program that went into this shines through here.

I also want to say that going forward we have complete confidence in the AbbVie commercial team. We've been interacting with them for, boy, I'd say, nearly the last two years and we've seen a lot of the work that has started to come out with ORILISSA and the work that Rick Gonzalez talked about that you're going to see over the next

several months. And so we have nothing but confidence in AbbVie and how they will handle this launch and the trajectory of ORILISSA.

Now, I would like to switch gears and let's talk about Neurocrine. And so I want to take a step back. This really is a special and unique time for any biotech company. Calls like this, the quarterly earnings calls that go over just the past three months, but this is, as I said, is a very special moment in time and I don't want it to get lost as we go into the details over the next hour.

We are a company that is in the very early stages of a continuing extremely successful launch and with a product that treats a disease that was previously untreatable. And if that isn't enough, we have a second drug approved that will change the lives of millions of women. Both of these drugs were discovered here at Neurocrine. I think I speak for all of us, both current employees and former employees that we are both proud and humbled to be in this position.

So, with that, let's get into the details. And I'd like to start by turning the call over to Matt, and he can talk about what a great quarter this has been.

Matthew C. Abernethy

Chief Financial Officer, Neurocrine Biosciences, Inc.

Yeah. Thanks, Kevin. Good afternoon and thank you for joining our second quarter 2018 earnings conference call. Neurocrine has had a tremendous start to 2018 with INGREZZA's continued success, ORILISSA receiving FDA approval, positive Phase III data for uterine fibroids and a green light from the FDA to proceed towards an NDA submission for opicapone.

During the second quarter of 2018, INGREZZA saw script volume increase to approximately 16,700 scripts, resulting in $96.9 million in net product sales. This compares to 12,500 scripts and $71.1 million in net product sales for the first quarter of 2018. Through the first six months ended June 30, 2018, INGREZZA net product sales were $168 million compared to $6.3 million for the same period last year.

As a reminder, INGREZZA was made available for commercial distribution on May 1, 2017. The TRx upward trajectory during the second quarter reflect steady new patient flow and uplift coming off of payer-related seasonality in Q1 and continued positive persistence trends. We expect persistent trends to wane further over time as we have more patients on drug longer.

Regarding net revenue per script for Q2, we experienced a slight increase from approximately $5,700 per script in Q1 2018 to approximately $5,800 per script in Q2 of 2018. The increase is primarily a reflection of lower impact from the Medicare Part D donut hole as compared to Q1. This was partially offset by the continued decrease in scripts being filled as 240 milligram capsules versus the 180 milligram capsule. Scripts being filled with 240 milligram capsules was in the mid-single-digits of our total scripts during the quarter and expect this to continue to decrease throughout 2018.

Net loss for the quarter was $5.9 million or $0.07 loss per share compared to a net loss of $60 million or $0.68 loss per share for the same period in 2017. For the six months ended June 30, 2018, the net loss was $47.7 million or $0.53 loss per share compared to a net loss of $138.3 million or $1.58 loss per share for the same period in 2017. Recall that INGREZZA was launched in the second quarter of 2017, so when comparing 2017 to 2018 there is only $6 million of corresponding Rx revenue during the first half of 2017.

Research and development expenses were $37 million during the second quarter of 2018 compared to $21.9 million during the second quarter of 2017. The increase in R&D expenses during the period is a reflection of the continued progress being made across our pipeline, including Tourette's, CAH and also preparation for our anticipated 2019 opicapone NDA filing. In addition, we continue to invest preclinically with a goal of at least one IND in 2018.

For the six months ended June 30, 2018, R&D expenses were $85.9 million as compared to $73.8 million for the same period last year. The increase from the prior year was primarily a result of an increase in the previously mentioned clinical program activity and $8 million nonrecurring stock compensation charge in Q1 of 2018, as well as a $10 million milestone payment to BIAL in Q1 of 2018. This year-over-year increase in R&D during the first half of 2018 was partially offset by the timing of a $30 million exclusive licensing payment made to BIAL for opicapone in the first quarter of 2017.

Sales, general and administrative expenses increased to $60.9 million for the second quarter of 2018 from $41.7 million for the second quarter of 2017. For the six months ended June 30, 2018, SG&A expenses were $119.6 million compared to $69.7 million for the same period last year. The increase in SG&A expenses across both periods is primarily due to commercialization activities for INGREZZA. Our cash, investments and receivable positions as of June 30, 2018, was over $800 million, positioning us well to execute our near-term company strategy.

Now, a few comments as we look ahead towards the second half of 2018. With the approval of ORILISSA, we will recognize revenue during the third quarter for the $40 million event-based milestone due to Neurocrine under our collaboration agreement with AbbVie. In addition, we will also begin earning a tiered royalty from AbbVie based upon their net sales of ORILISSA following their launch in August.

As it pertains to INGREZZA, we remain encouraged by our progress in the marketplace and also how we are executing our sales force expansion plan which we expect to have completed entering the fourth quarter of 2018. Specific to INGREZZA third quarter net product sales, we expect there to be continued new patient demand and an increase in overall script volume. As with all launches, certain factors cause fluctuations in growth quarter-to-quarter.

For us, the items we're managing through heading into Q3 include the possibility of distraction from our sales force expansion, seasonal dynamics and the continued decline in less scripts being filled as two 40s. The long-term potential within INGREZZA is robust. But as always, I want to make you aware of the key items we're focused on specific to Q3. Regarding operating expenses for 2018, we still expect our operating expenses to fall within our previous guidance range of $395 million to $420 million.

With that, I will now hand the call over to our Chief Commercial Officer, Eric Benevich.

Eric S. Benevich

Chief Commercial Officer, Neurocrine Biosciences, Inc.

Thanks, Matt, and hello to everyone joining us on today's call. The second quarter of 2018 was a great quarter for our INGREZZA TD launch and I couldn't be more proud of the performance of our team and their effort to help the many patients suffering from TD. As of Q2, we have now been on the market for approximately a year and the launch continues to exceed expectations. As Matt said, net sales in Q2 were nearly $97 million, representing a 36% increase over the previous quarter.

In over our first four full quarters of our launch, we have generated $278 million in net sales. A key metric of assessing performance is the impact to patients, which is reflected in our total prescriptions which increased 34% over the prior quarter to 16,700. New patient starts remained steady and patient persistency continues to be in line with our expectations as the launch matures.

From a prescriber perspective, our TRx growth is coming from both new prescribers and prescribers expanding use within their practices, as they get experience with INGREZZA. We see ample opportunity over the coming years to expand both the breadth and depth of our prescriber base, which we believe will be realized through continued disease state awareness, education and real-life clinical experience with INGREZZA.

The INGREZZA brand continues to see favorable coverage across all payer segments, with the vast majority of prescriptions requiring a prior authorization confirming a diagnosis of TD. Through the first year of the launch, approximately 80% of written prescriptions have led to a dispense medication and INGREZZA remains affordable for patients with over three-quarters of them paying less than $10 out-of-pocket per month.

INGREZZA is the market leader in TD and we intend to build on that momentum. Our previously announced sales force expansion is right on track. We have received literally thousands of applications for less than 100 new sales positions. We're currently interviewing many highly qualified applicants across the country with extensive experience in neurology and psychiatry, consistent with our existing sales team.

As Matt mentioned, we're taking measures to minimize distraction from this expansion on our current sales team and existing customers. And we expect to deploy our newly expanded team in Q4. Combining the new team members with our highly capable existing sales force gives us great confidence that we'll continue to make significant progress in developing the TD market over the years ahead.

Going forward into the balance of the year, we are focused on executing our plan of continuing our TD educational efforts. We are helping healthcare providers recognize the range of presentations and severities of TD, helping them appreciate the multifaceted burden that TD can place on patients and their loved ones, and urging them to identify and treat appropriate patients with INGREZZA, the first FDA approved medication for TD and the only treatment option that offers robust efficacy, no-box warning, favorable tolerability, and simple once-daily dosing without complex titration.

So, in summary, Q2 2018 was a great quarter for the INGREZZA brand and for our company. We attribute these strong results to an attractive drug profile, a great team and also focused execution of our market-building strategy. Approximately a year into our launch, we continued to deliver consistent and steady growth. And most gratifying to me and the rest of our team is that we have helped thousands of patients suffering from TD. We are truly living up to our shared aspiration of delivering on hope.

So, with that, I'll now turn the call over to Eiry Roberts, our Chief Medical Officer, to discuss progress with our clinical programs. Eiry?

Eiry W. Roberts

Chief Medical Officer, Neurocrine Biosciences, Inc.

Thank you, Eric, and good afternoon to everyone on the call. I'm pleased to be able to provide an update on progress this quarter across our clinical programs. For INGREZZA, at the American Psychiatric Association Annual Meeting in May, we shared new data from the RE-KINECT study.

This study is the largest real-world screening study of patients with clinician-confirmed possible tardive dyskinesia designed to provide valuable insight into the impact of involuntary movements on the quality of life for patients taking antipsychotic medication. Data from this study demonstrate that nearly 28% of the study population treated with antipsychotics had clinician-confirmed possible tardive dyskinesia.

In addition, over half of the patients with possible TD experienced uncontrollable movements in two or more body regions. New data from the KINECT 4 study were also presented at APA demonstrating that long-term treatment with INGREZZA provided sustained, clinically meaningful improvement in tardive dyskinesia without the emergence of new safety signals.

Turning now to the Tourette indication for valbenazine, the T-Force GOLD study evaluating optimized doses of valbenazine in approximately 120 pediatric patients with Tourette syndrome has continued to progress and we remain highly confident in our plan to release top-line data from this study late in 2018. With these data in hand, we will meet with the FDA in the first part of 2019 to discuss the path forward to submitting an sNDA in Tourette syndrome for valbenazine.

In recent weeks, the T-Force PLATINUM study began patient enrollment activities with good success to-date. As previously described, T-Force PLATINUM is a double-blind placebo-controlled randomized withdrawal study of valbenazine in approximately 180 pediatric patients with Tourette syndrome. Enrollment in this study is progressing to plan and we anticipate having top-line data available at the end of 2019.

In addition in the second quarter, we commenced enrollment into the open label extension study, T Force GOLD Plus, for Tourette syndrome patients. Subject to complete participation in the T Force GOLD study are eligible to roll over into participation in this open label extension study for an additional six months of treatment with optimized doses of valbenazine. The study will collect longer-term safety and tolerability data in children and adolescents as well as providing useful information about the maintenance of efficacy in these patients over the six months period of dosing.

For opicapone, we remain on track with the work required to complete the NDA dossier and to support submission for this molecule in the first half of 2019. Of note, we recently successfully completed dosing in the last of the planned clinical pharmacology studies. Final reports from these studies will be included in the NDA submission.

Turning now to our CAH program and the Phase II proof-of-concept study examining the pharmacokinetics, pharmacodynamics and tolerability of NBI-74788 in adult patients with classic 21-hydroxylase deficiency. As mentioned last quarter, site initiation was slower than originally planned for this study, but we now have our sites active and focused on enrollment. We anticipate that initial data from the study will be available later this quarter with the full study completed in quarter four.

With these data in hand, we plan to meet with the FDA to discuss the path forward for the clinical evaluation of this molecule as a novel treatment for both adults and children with congenital adrenal hyperplasia. We remain very encouraged by the progress we're seeing across our clinical development portfolio and look forward to sharing data with you later in the year.

With that, I'll now hand the call back over to Kevin for some closing remarks.

Kevin Charles Gorman

Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

Thank you very much, Eiry. So, obviously, as we got from Matt and from Eric and Eiry, a very productive quarter for us. We're on track to continue to bring new and important medicines to patients and in multiple indications.

So what I'd like to do now is open up the call to everyone's questions.

QUESTION AND ANSWER SECTION

Operator: Certainly. [Operator Instructions] Our first question comes from Geoff Meacham with Barclays. Please go ahead.

Geoff Meacham
Analyst, Barclays Capital, Inc.
Q

Good afternoon, guys. Congrats on the quarter and thanks for the question. Just on commercial INGREZZA, I know I always ask on duration trend, so if we can get specifics on that it'd be great. Then for this quarter was there any maybe call out among psychiatrists or even among patients that could represent a tipping point in demand just given the sequential trend? I know, Matt, you called out some seasonality but is there anything outside of that? And I have one more follow-up.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.
A

Yes. So, Geoff, can you clarify your question? It was about the duration of treatment?

Geoff Meacham
Analyst, Barclays Capital, Inc.
Q

Yeah, just persistent trends and then anything that you call out with respect to a potential tipping point in demand.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.
A

Okay. So with regards to persistent trends, we went into the launch expecting that persistence with our medication, INGREZZA, would likely be consistent with what we see for other medications that are typically used in these patient populations, antipsychotic medications, antidepressant medications and so on. And that's approximately – we've seen though maybe a little bit better than what we expected.

Certainly as we get more and more patients that have been on drug for longer, the averages come down. But thus far we've been really pleased with the persistence that we've seen and we think that it may be due to two factors. One is that this is a highly symptomatic condition. And we know that based on the extension of the KINECT 3 study that when patients go off their medication as they did at the end of the open label extension, the TD movements return fairly quickly. And the other thing is that we've got a distribution model where patients are being contacted by the pharmacy and that tends to help keep them on drug. So, overall, we're happy and pleased with the persistence that we're seeing at this stage of the launch.

And the second was really around a question, I guess, you had was really around the tipping point. I don't think of it in terms of tipping point. I view launches as sort of a series of surges so to speak as you identify opportunities and you continue to tighten up your messaging and your targeting and so on. So I think that we would expect to see variability or fluctuation from month-to-month or from quarter-to-quarter in terms of what that growth rate

looks like but we expect to see continued growth. And obviously we're in it for the long haul in terms of making the investment, educating our customers about TD and helping them to identify appropriate patients for INGREZZA. So I hope that that addresses your question.

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.
A

I think the only thing I'd add, Geoff, is we made the decision to invest in the sales force last quarter and that is a clear sign to our belief in the market opportunity here and that, as Eric said, just the long-term potential we see as very significant.

Geoff Meacham
Analyst, Barclays Capital, Inc.
Q

And just related to that, Matt, just as a follow-up for you or for Kevin. On the P&L, you guys have been pretty disciplined on the cost side and it looks like even before elagolix economics kick in you're almost profitable. So, the question is how much of a priority going forward is the earnings trajectory versus the INGREZZA launch and/or the pipeline? It just seems like a range of approaches to investments in the business when SMID-cap transitioned to close to profitability.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.
A

Yeah. So, I'll jump in first, Geoff, and just say that we're investing in the company and we're going to make those smart investments in the company. Obviously, first and foremost is in our internal R&D organization and our commercial organization to make INGREZZA as successful as possible and then also to bring all of our programs forward as rapidly as possible.

And then secondarily we are or second we are going to be looking on the outside for other compounds and programs to bring into the company. So, profitability isn't something that we either avoid or try to maximize actually at this point. Where we look at it is that the cash flows that we have coming in from INGREZZA and that we will have coming in from ORILISSA are just going to make us that much stronger in being able to develop our pipeline.

Geoff Meacham
Analyst, Barclays Capital, Inc.
Q

Okay. Thanks.

Operator: Thank you. We'll go next to Brian Skorney with Baird. Please go ahead.

Brian P. Skorney
Analyst, Robert W. Baird & Co., Inc.
Q

Hey. Good afternoon, guys. Thanks for taking my questions. I just wanted to follow up a little bit on some of the commentary around pricing and prescription and what we could anticipate in the future. I guess, any comment on what the payer mix you're currently seeing is and what you think that may be switching to if there's any switching in terms of private versus public and thoughts around contracting in TD? And also want to kind of follow that up with whether or not you're seeing any penetration from AUSTEDO in terms of growing market share and if you're seeing if that market share is coming from TD patients new to any treatment or primarily from an INGREZZA failure population? Thanks.

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

All right, Brian. I think you had four or five questions in there, which we always appreciate. I'll take the first one on sort of our net revenue per script, gross to net, and Eric will take the contracting and commentary around competition.

So, from a gross to net perspective and payer mix, we are seeing some fluctuation quarter-to-quarter. For example, as you get on different state Medicaid plans, you can see Medicaid mix increasing because of that. We've not provided historical insight into what our exact mix of government versus private and we're not intending to do that here. So, I'd call it we are having some change but not major change at this point in the launch.

And then, from a gross to net perspective, we've not been at a place where we've had the contract yet. In addition, as I alluded to on the call, we do still have mid-single-digit percentage of our total scripts going out as 240 milligram capsules which gives us a bit of a lift on that net revenue per script but we expect that to go down throughout 2018. So, Eric can comment on contracting and competition.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. So just want to sort of piggyback on what Matt said. We're over a year into our launch and we haven't been contracting with payers. We feel good about the value proposition of INGREZZA. And, certainly, we feel that the reimbursements have been favorable thus far and it's appropriate to have doctors confirm a diagnosis of TD before the health plan is going to reimburse for that claim. So thus far a year-plus into our launch we haven't been contracting with payers and we're happy with the access. We think that this is a really favorable situation.

Second thing with – I guess sort of the fourth part of your question was the competition piece. We actually view our main competitor as apathy or inertia. In other words, physicians and other healthcare professionals that do nothing and historically that's been sort of the standard of care for TD and we're changing that with education. And when we think about motivating our customers to make that diagnosis and treat patients that's a win for the patient.

We know that there is a reformulated tetrabenazine product that's also on the market with the same indication. We don't hear a lot about it from our customers. Frankly, we don't focus on it. So we're really facing forward. We're delivering on our strategy of educating customers. And we're really pleased with the product profile that we have. And we think that that's really the main reason – along with our execution the main reason that we're seeing the results that we have so far.

The strong efficacy, the lack of a box warning, the tolerability profile and the once-daily dosing with no complex titration, those are all reasons that we're seeing the uptake that we have thus far. So with regards to the other company and their product we'll let them comment on where they think they're getting the bulk of their business. But we're focusing on adding new patients and giving the existing patients the best possible experience with INGREZZA.

Brian P. Skorney
Analyst, Robert W. Baird & Co., Inc.

Q

Thank you.

Operator: Thank you. We'll go next to Tazeen Ahmad with Bank of America. Please go ahead.

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch

Q

Good afternoon and thanks for taking my questions. A couple for me, can you give us an update on where you are? You talked about your sales force expansion now being underway but how much of that is complete and how much of that might have contributed to your strong quarterly results? And then I have a couple of follow-ups.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. So, hi, it's Eric again. We're in the midst of it right now. We're interviewing candidates, as I mentioned in my prepared remarks. They haven't been on-boarded and haven't started the training yet. So the results that we reported out for Q2 don't reflect that sales force expansion. In fact, what we're really focused on in addition to identifying the best candidates is minimizing any distraction factor to our existing team and customers.

So, I was really pleased with the results for Q2 as you can imagine, especially in light of the possibility of some distraction coming from that expansion. We expect to be able to put the new expanded team in the field early in Q4. And obviously that's heading into the holidays. It's going to take a little bit of time for the new hires to get around and meet all their customers. So there's going to be a bit of time lag between when we put the new field team in place and when we start to see the impact of that. But so far so good and I've been really pleased with the quality of the candidates that we've been able to attract into the interview process.

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch

Q

Okay. And related to that, is your plan to have sales rep focus on fewer doctors per targeted area or are you trying to have multiple points of contact in the same areas?

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. So the way I would characterize it is that even though we're going to have smaller territories the number of physician targets and institutional targets will be approximately the same. In other words, through the first nine months or so of the launch, we identified a lot more attractive HCP targets and have pulled them into our target universe.

We don't have the bandwidth to cover everyone that appears to be valuable from an INGREZZA perspective. And so that's part of the rationale for the expansion is that there is more opportunity than what we had originally anticipated before we had our field sales team out there calling on customers. So smaller geographies, similar number of physicians and allied health professionals and institutional accounts that they'll be covering in those territories.

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch

Q

Okay. Thanks, Eric. And then one for Kevin. On T-Force GOLD, what top-line information do you expect to release when we expect to see the data I guess by year-end? And what would be next step following that if you could remind us assuming that the data is published?

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

Well, I'll start to answer and then if Eiry doesn't grab me by the throat I guess I'll finish. So what we'd expect to do is what we have done in the past. We will show on the primary endpoint. Yale Global Tic Severity Scale, YGGTTS (sic) [YGTSS] (33:40), is going to be the change from baseline as compared to placebo. And so, you will get that by magnitude and P value.

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.
A

Correct. That's correct. And as I mentioned in the prepared remarks, we will then take the entirety of that dataset from the study and take that to talk with the FDA in the first part of next year in order to understand the path to supplemental NDA submission.

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch
Q

And it is still your growing assumption that if the data is positive that this could serve as your pivotal?

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.
A

It is a pivotal study and we intend that to be the strategy that we're going forward with.

Tazeen Ahmad
Analyst, Bank of America Merrill Lynch
Q

Okay. Thank you.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.
A

Thank you, Tazeen.

Operator: We'll go next to Anupam Rama with JPMorgan. Please go ahead.

Anupam Rama
Analyst, JPMorgan Securities LLC
Q

Hey, guys. Thanks so much for taking the question. Just a quick one for me. You guys kind of commented on this in your opening comments. But when you think about those accounts where you have the longest relationships or maybe strong initial uptake out of the gate for INGREZZA last year, how would you describe the level of penetration into those accounts? How much room is there to grow within those accounts? Are you seeing any type of plateau effect? What are the kind of trends there? Thanks so much. No follow-ups.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.
A

Okay. So, I would say there's still considerable room to grow. And the reason is that in some of these accounts you have multiple providers and extended staff. And so, our typical model is to go in and to start to educate the prescribers but also the integrated care team, include the nursing staff, case managers and therapists and so on.

And so, what this really requires is for everyone to be aware of TD, to understand TD, to recognize TD symptoms and to bring it to the attention of the prescribers. And with multiple prescribers in these clinics, you're kind of bringing them along at different rates and certainly there's a large number of patients in some of these community

mental health centers that still could benefit from screening and treatment with INGREZZA. So, I think there's still a lot of upside even in the institutional accounts where we've already gotten good traction.

Anupam Rama
Analyst, JPMorgan Securities LLC

Q

Thanks so much for taking the question.

Operator: We'll go next to Jay Olson with Oppenheimer. Please go ahead.

Jay Olson
Analyst, Oppenheimer & Co., Inc.

Q

Hey, guys. Congrats on the quarter and thanks for taking my questions. I was wondering if you could break down the 16,700 TRxs into NRxs and refills and also maybe comment on the mix of prescribers between neurologists and psychiatrists. And then also, I was wondering if you could just talk about the impact that your educational program for psychiatrists has had, the program that you rolled out at APA back in April.

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

Hey, Jay. This is Matt. Thanks for the question. We aren't providing the breakdown between NRxs and refills. But hopefully you can see in our sequential trend up, it would show that we had a good flow of new patients. And as we said in our comments, persistence trends have been higher than what we expect from a long-term perspective once patients are in drug longer. So, we feel really good with where we're at both on new patient adds as well as the refill rates.

From a sales mix perspective, similar to what we've said in the past, our call points are, call it 80%/20%, 80% sites, 20% neurologists. And that's pretty reflective of what you would see in our underlying script volume. From an educational program perspective, I'll hand it over to Eric.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. I'll just say that we've been very active in terms of peer-to-peer education. Certainly, having a presence at the national and regional professional medical meetings such as AAN and APA helps but the bulk of our prescriber universe doesn't go to those meetings. And so, we've been doing a lot of work with our speakers' bureau, bringing in, for example, neurologists to speak to psychiatrists' audience, bringing psychiatrists to speak to psychiatrist audiences and so on.

And so that's been really valuable. As physicians learn about a new medication and a new way to treat a previously untreatable condition, they rely on the experience of others that have started to get some clinical experience. And so, at this stage of the launch, there's a lot of peer-to-peer activity as part of our overall strategy.

Jay Olson
Analyst, Oppenheimer & Co., Inc.

Q

Great. Thanks for taking the question.

Operator: We'll go next to Phil Nadeau with Cowen & Company. Please go ahead.

Phil Nadeau
Analyst, Cowen & Co. LLC

Q

Good afternoon. Congrats on a good quarter, and thanks for taking my question. First one on the overall size of the tardive dyskinesia market. Prior to the launch, I believe you put figures that suggested there were maybe 500,000 patients with tardive dyskinesia in the U.S. and 280,000 who were moderate to severe, so appropriate for treatment. How have your understanding of those figures changed as you've been in the market for a year and in particular as you found more physicians that may be treaters of these patients?

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. I think our understanding of the overall prevalence is the same as what it was. Certainly, we've relied on multiple publications in the medical literature to help us size the market. Certainly going into this launch, it was our belief that the majority of these patients were undiagnosed.

So our focus is not only on what's the overall size of the market opportunity, which we think is considerable, but really growing that immediately accessible patient pool, which is the diagnosed patients that are under the care of physicians that we can reach. Physicians and other healthcare professionals, I should say.

So as we expand that addressable patient pool, we're both increasing the opportunity in the near-term and we're focusing on penetrating that near-term opportunity. So sort of a two-pronged approach for us, grow the pie and take a slice of the pie.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

And, Phil, just one thing I want to follow-up on is that again the appropriateness of a patient for treatment isn't really correlated with the severity of their tardive dyskinesia. There are – and as we have seen that have gone on treatment both by the physician and by the patient population who would be categorized as mild tardive dyskinesia have found significant benefit from the drug. So I just wanted to jump in with that.

Phil Nadeau
Analyst, Cowen & Co. LLC

Q

Got it. That's helpful. And second on pricing. You've mentioned that pricing picked up actually quarter-over-quarter due to donut hole and other seasonal effects. Aside from the change in the 2 times 40 milligram pill that you expect to go forward, are there other seasonal effects we should be aware of that would affect the price per script through the remainder of the year?

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

No. I think it's primarily the two 40s. And as Eric mentioned earlier, we were not really in a place where we're contracting yet. That could be something that would have some sort of an impact but at this point I would point to the two 40s as probably being the biggest driver.

Phil Nadeau
Analyst, Cowen & Co. LLC

Q

Got it. Okay. And then one last question, on ORILISSA, you mentioned that the duration that is on the label is really a recommendation not a restriction. I'm curious what you think payers are likely to do with those

recommendations. Do you think that the payers will give patients hard time should they want to stay beyond the recommended duration or is it just too early to know?

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

So, Phil, I think that Rick Gonzalez actually talked about their reception from payers thus far and their work with them leading up to the launch and it seems to be very good. He's very encouraged by it. You would anticipate that the payer environment is going to change and payers are going to put hurdles in where they think they can.

But, honestly, you've had women who have been suffering from the debilitating pain of endometriosis for years. Now they're getting an oral product that for the first time they can take, relatively few side effects and it has outstanding efficacy. It would be hard to believe that after two years of such relief that a payer would be able to put a substantial hurdle in front of that patient continuing on treatment.

Phil Nadeau
Analyst, Cowen & Co. LLC

Q

That's very helpful. Thanks again for taking my questions.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

Thank you.

Operator: We'll go next to Biren Amin with Jefferies. Please go ahead.

Biren Amin
Analyst, Jefferies LLC

Q

Hey, guys. Thanks for taking my question and congrats on the quarter. I guess of the new patients coming on to INGREZZA, what percentages are coming from AUSTEDO? What percentage are coming from off-label therapies and which percentage are new patients?

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

Yeah. Hey, Biren. Thanks for the question. When we do our surveys and have read other surveys that have been done very little switching between the two – between us and AUSTEDO at this point. From a off-label use, we do hear some instances that it could be used on occasion off-label. We do not incentivize our market in that regard and would be a very, very low percentage of any business that we do, but are very careful around that obviously. And then, from NRx as I told Jay, we've not provided that mix.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. The only other thing that I would add to Matt's comments is that with our focus on helping our customers with recognition and diagnosis, the vast majority of patients that again started on INGREZZA are newly started on treatment for their TD.

Biren Amin
Analyst, Jefferies LLC

Q

Got it. And then, I guess, can you tell us or give us any color on what percentage of scripts are coming from large-volume centers versus smaller community clinics?

Matthew C. Abernethy
Chief Financial Officer & Director, Neurocrine Biosciences, Inc.

A

No, but what we have commented on that we see scripts are not heavily, heavily concentrated when you dig in to our customer base, very spread out.

Biren Amin
Analyst, Jefferies LLC

Q

Yeah.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

And the reality is that in neurology and psychiatry, most of these physician practices are small group practices. And so, that's where we're getting the bulk of our prescriptions.

Biren Amin
Analyst, Jefferies LLC

Q

Got it. Okay. And then, maybe just a follow-up on T-Force PLATINUM in Tourette's, are you randomizing patients at week 12 if the patients see a response on Yale Global Tic score with INGREZZA? And I guess, of the 180 patients enrolled, how many do you expect to enroll into that randomized phase?

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.

A

Thank you for the question. We are randomizing patients on the basis of seeing a favorable response to valbenazine in the first 12 weeks of treatment. That actually is not necessarily using the Yale Global Tic Severity score. It's actually more an assessment – physician assessment of clinical improvement. And we haven't actually released exactly what we anticipate as being the rollover rate. We obviously powered the study based on what we believe would be the clinical response rate in this disease area. And we anticipate seeing at least that number of patients rolling over. But we haven't released exactly what the number is that we believe will roll over.

Biren Amin
Analyst, Jefferies LLC

Q

Got it. Thank you.

Operator: We'll go next to Alan Carr with Needham & Company. Please go ahead.

Alan Carr
Analyst, Needham & Co. LLC

Q

Hi. Thanks for taking my question. Wonder if you could go over your BD strategy at this point. Your cash balances is getting bigger here, so I'm wondering if your BD strategy is evolving. And then also can you give us a sense of timing for the work that Mitsubishi's doing with INGREZZA in TD? Thanks.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

So, Alan, I'll take that question. This is Kevin. The BD strategy remains the same as it has for the past couple of years. It just means that the size of opportunities that we'll look at have gotten larger. So we are looking for and I would say in order of priority very good [ph] signs (47:03) that brings a meaningful – has the possibility of bringing a meaningful product or products to patients, not me-toos and not just incremental changes. And that our investors will appreciate the value that the transaction would bring.

So there's a lot of great work that's being done outside of Neurocrine's four walls and we're just very active in looking at all of that and we'll be as creative as we need be in order to do a deal. But it has to be the right deal, and I think I just gave you the three broad [ph] SWOTs (47:44) of what we look at.

As far as Mitsubishi is concerned, they're in a Phase III clinical trial now currently. I don't have the timing of when they expect a read out from that trial yet. But they've been working very diligently towards that and it's nice to have our partner in Phase III so quickly.

Alan Carr
Analyst, Needham & Co. LLC

Q

All right. Thanks for taking my questions.

Operator: Thank you. We'll go next to Sumant Kulkarni with Canaccord. Please go ahead.

Sumant Kulkarni
Analyst, Canaccord Genuity, Inc.

Q

Hi. Thanks for taking my questions. My questions are on opicapone. So other than the dosing schedule, what are the key clinical hooks that could help this product penetrate what is essentially a highly genericized market which also appears to be shrinking from an IQVIA or IMS scripts point of view?

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

Sorry. Could you repeat that?

Sumant Kulkarni
Analyst, Canaccord Genuity, Inc.

Q

Sure. So, on opicapone, other than dosing schedule, what are the key clinical hooks that could help this product penetrate what seems to be a highly genericized market that is shrinking from an IQVIA scripts point of view?

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

A

Everyone wants to jump in right now, so...

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.

A

So let me start with some of the clinical attributes that we think are going to be important from a patient point of view and then Eric and Matt will have comments on other elements here. As you know, opicapone is currently available already in Europe as in the hands of our partner, BIAL.

Clinically, what the Phase III program has demonstrated is a very favorable benefit-risk profile associated with the efficacy improvement that is seen and also the tolerability profile, particularly when you look at that in the context of the class of COMT inhibitors that are currently available and some of the inherent tolerability or safety risks associated with that class.

We do believe that given the burden of treatment for these patients with Parkinson's disease that the once-a-day dosing is actually a very critical differentiator. And we also know in our understanding of the Parkinson patient population that there is still significant unmet medical need in the context of these motor fluctuations and that they can be very damaging, given the unpredictability of how these fluctuations and off-times comes on for patients with Parkinson's disease.

So we're very excited about opicapone and the opportunity and value that it can bring to patients. We believe we have a very robust clinical data package that was put together by our partner, BIAL. In addition, the other comment I'd make is obviously one of their Phase III programs included a direct comparison to the leading COMT inhibitor, entacapone, and the drug performed very favorably in that comparison. So clinically, we're very excited in that regard.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. This is Eric. The points that I would add on to what Eiry made was that from a commercial perspective when we looked at the opportunity we viewed this molecule as essentially delivering on the promise of COMT inhibition. Robust efficacy with a favorable tolerability profile and, importantly, once-a-day dosing which are not options currently within the COMT class and the other drug classes that are out there have issues and we certainly heard that from the movement disorder neurologists that we consulted with.

So, we think that there's an opportunity to offer unique innovative therapy for these patients. And in addition, it's a nice strategic fit with our current platform for INGREZZA with the coverage that we have of essentially the entire movement disorder neurology community. So, we look forward to continuing to prepare for the launch as we file our NDA application next year. But we think that this is going to be an exciting opportunity for our team to demonstrate what we can do with the second product.

Sumant Kulkarni
Analyst, Canaccord Genuity, Inc.

Q

Thanks. And now that you're close to the filing, could you share your latest thoughts on potential pricing of peak sales for opicapone?

Matthew C. Abernethy
Chief Financial Officer, Neurocrine Biosciences, Inc.

A

No. We're not at a place yet to be able to provide that insight. As we get closer to launch, we'll provide insight – as we get closer. Thank you.

Sumant Kulkarni
Analyst, Canaccord Genuity, Inc.

Q

Thank you.

Operator: Our final question comes from David Amsellem with Piper Jaffray. Please go ahead.

David A. Amsellem
Analyst, Piper Jaffray & Co.

Q

Thanks. Just a couple, so first, have you or are you willing to disclose specifics on the statistical powering of the T-Force GOLD study? And then secondly also, Tourette's-related. Do you have data on how many Tourette's patients are getting XENAZINE off-label? And then lastly regarding the payer landscape in Tourette's, can you talk about how much more restrictive it could be relative to tardive given that you have neuroleptics approved for Tourette's? Thanks.

Eiry W. Roberts
Chief Medical Officer, Neurocrine Biosciences, Inc.

A

Yeah. So, let me address the first one. This is Eiry here. We have not articulated out detailed thinking about the power calculation for this study. I will say that the study, given it's a pivotal study and provides the basis for our discussion with the FDA around the sNDA, is adequately and strongly powered to deliver on the primary endpoint, as Kevin articulated, which is a change from baseline on Yale Global Tic Severity score for the treatment group compared to placebo.

Eric S. Benevich
Chief Commercial Officer, Neurocrine Biosciences, Inc.

A

Yeah. And I think the second half of your question was really related to what the payer environment might be like for the Tourette indication. It's early days yet and we've had some initial discussions with payers. But I can say that they recognize that the currently available treatments are not being utilized to the extent that they could be simply because we're talking about antipsychotics being used in children. And there's a reluctance to use antipsychotics in children because of all the safety issues that we're all well aware of.

So we're excited about the opportunity to bring a product to that patient population with a different mechanism of action and we think a favorable safety profile. And we think that the plans will be reasonable, at least that's the expectation that we have so far based on our interactions in terms of making sure that patients have access to an effective safe treatment.

Operator: Thank you. It appears we have no further questions at this time. I'll turn it back to Mr. Gorman for any additional or final remarks.

Kevin Charles Gorman
Chief Executive Officer & Director, Neurocrine Biosciences, Inc.

Thank you. For over a decade we've talked about INGREZZA and ORILISSA as each one being a pipeline and a program. And now that fruition is coming true. TD and endometriosis are just the first indications for INGREZZA, next comes Tourette's; and for ORILISSA, uterine fibroids. And stay tuned to both ourselves and AbbVie for even additional indications in the future with those.

And in addition to those, our pipeline is robust with opicapone that we'll be filing the NDA on next year in CAH which we're moving along. This is a pipeline that if it just stayed static would result in four compounds on the market in six indications in just four short years. But it's not going to stay static.

We're going to have more compounds continuously coming from our R&D group. And as I've told you, we still anticipate at least one more coming this year. And as we've talked about on this call, we're very active on the business development front. So, as enviable a position in, gosh, 10 years ago, I never thought we'd be in this position right now. But it is an enviable position but it's one that we continue to work at and we believe we'll just get better and better with time.

So, in closing, I would like to again thank our partner, AbbVie. And I want to thank all of our Neurocrine employees. It's their dedication and talents that are the reason for our success and we really do look forward to many more successes in the future. So, thank you very much for everyone's attention. It's been a pleasure speaking with you today.

Operator: Thank you. This does conclude today's conference. We appreciate your participation. You may disconnect at any time and have a wonderful day.