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 earliest event reported): September 9, 2020

NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**0-22705**	**33-0525145**
(State or Other Jurisdiction of Incorporation)	**(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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value	NBIX	Nasdaq Global Select Market

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 (see General Instructions A.2. below):

☐ 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 7.01. Regulation FD Disclosure.

On September 9, 2020, Neurocrine Biosciences, Inc. (the "Company") presented at the Citi 15th Annual BioPharma Virtual Conference.

A transcript of the above-referenced presentation is attached as Exhibit 99.1 to this report and is incorporated in this Item 7.01 by reference. A link to the webcast of the presentation will be available on the Company's website at www.neurocrine.com for approximately 30 days.

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

In addition to historical facts, this Current Report on Form 8-K contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to: the benefits to be derived from the Company's products and product candidates; the value the Company's products and/or the Company's product candidates may bring to patients; the continued success of INGREZZA; the timing of the Company's launch of ONGENTYS; the Company's financial and operating performance, including the Company's future expenses; the Company's collaborative partnerships; expectations regarding the impact of COVID-19 on the Company's business; expectations regarding the Company's ability to adapt the Company's business to the evolving COVID-19 pandemic, mitigate its impact on the Company's business and maintain business continuity, including the Company's ability to protect the safety and well-being of the Company's employees, to continue to support uninterrupted supply of INGREZZA, including patient and healthcare provider access to INGREZZA, to continue the Company's ongoing clinical trials and other development activities, and to otherwise advance the Company's business objectives; and the timing of completion of the Company's clinical, regulatory, and other development activities and those of the Company's collaboration partners. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: the Company's future financial and operating performance; risks associated with the commercialization of INGREZZA and the Company's other products; risks that the launch of ONGENTYS may be delayed; the impact of the COVID-19 pandemic and efforts to mitigate its spread on the Company's business; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; risk and uncertainties related to any COVID-19 quarantines, shelter-in-place and similar government orders that are currently in place or that may be put in place in the future, including the impact of such orders on the Company's business operations and the business operations of the third parties on which the Company relies; risks related to the development of the Company's product candidates; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA and the Company's product candidates, and the Company's ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding the Company's products or product candidates; risks associated with the Company's dependence on AbbVie for the commercialization of ORILISSA and ORIAHNN, as well as the continued development of elagolix; risks associated with the Company's dependence on BIAL for manufacturing activities for ONGENTYS, and the Company's ability to manage BIAL; risks that clinical development activities may not be completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that the Company's product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that the potential benefits of the agreements with the Company's collaboration partners may never be realized; risks that the Company's products, and/or the Company's product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2020. The Company disclaims any obligation to update the statements contained in this Current Report on Form 8-K after the date hereof.

Item 9.01. Financial Statements and Exhibits.

Exhibit	Description
99.1	Transcript of Neurocrine Biosciences, Inc. presentation on September 9, 2020 at Citi 15th Annual BioPharma Virtual Conference
104	Cover Page Interactive Data File

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 thereunto duly authorized.

NEUROCRINE BIOSCIENCES, INC.

Dated: September 10, 2020

/s/ Matthew C. Abernethy

Matthew C. Abernethy

Chief Financial Officer
(Duly authorized officer and Principle Financial Officer)

Neurocrine Biosciences at Citi 15th Annual Biopharma Virtual Conference
September 09, 2020 @ 12:35PM ET

Corporate Participant
Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Conference Call Participant
Neena Bitritto-Garg *Citi Investment Research - VP*

Presentation

Neena Bitritto-Garg *Citi Investment Research – VP*

So hi everyone. Thank you so much for joining the 15th Annual Citi Biopharma Conference. I'm Neena Birtritto-Garg. I'm one of the SMID-cap biotech analysts here at Citi. So for our next fireside chat, I'm very excited to be joined by Kevin Gorman, CEO of Neurocrine Biosciences. So, you know, before we jump into questions, Kevin, would you like to give some opening remarks?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Sure. Neena, thank you very much to you and Citibank for the opportunity to speak here. Our investors get to see me and you kind of in our natural environs as we are now, so all the clutter of my office. I will be making forward looking statements so I would direct everyone to our recent SEC filings for all the proper warnings and cautions about the industry and Neurocrine in particular.

You know, Neena, what I'd like to convey is and we're gonna get into a lot of things here, but only probably just a small portion of Neurocrine because we've become a much larger and if you will, more complicated company. We have four commercial medicines right now… with our partner, AbbVie, we have ORILISSA and ORIAHNN that are on the market. There's obviously INGREZZA, which we've had on the market now for about three years. And we'll talk I'm sure a lot more about that as it come up. And then shortly we'll have ONGENTYS that is joining our portfolio and that we will be out there marketing and we'll be talking a lot more about that.

Beyond that though, our pipeline has developed pretty significantly in the last several months. And what's very nice about that is is that we've always had the goal of wanting to have a rich, deep, replaceable pipeline, that it'll be very, very obvious to patients, to providers, to payers, to our investors on just how replaceable our pipeline is and how it will continue to renew over the years and for the long term here. And so we now have a deep pipeline that.. that we've been developing. We have three late stage programs. We have five mid stage programs and then several earlier stage programs. So it's nicely balanced. We doing this with by having several partnerships that we've entered into that have brought us many of these compounds. And, you know, the medicines themselves and the opportunity they hold is extremely exciting. And hopefully we'll be able to get into some of those.
But beyond that, it's the partnerships that are actually very exciting to us. We've been able to partner with just some very, very nice companies and by nice I mean, creative, energized, really great technology, much like ourselves, a focus on the patients…wanting to get everything right and also whether they're big or small, very sophisticated companies. We know that there are challenges that are going to come along with everything no matter where you are, commercial or clinical stage or research stage. There's always going to be challenges. But when you look at our partnerships with Voyager, Takeda, Xenon, Idorsia… These are all just terrific companies to work with. The relationships with all of them, we really enjoy. They lift up our game, which is really nice when we interact with them, and, you know, it's a side and out side of the really interesting medicines that we're working on together. It's the fact that we get to learn from each other through these partnerships. And that just makes Neurocrine, I think, a much better company. And I certainly hope our partners are profiting from interacting with us.

And then finally, you know, when you when you have really interesting medicines, when you have, you know, terrific people within our company and outside our company working hard to bring these to patients. And then the third piece is being in a very nice financial position where you can continue to invest in yourself, whether it's internally or with external partners. It, you know, it really is even in these challenging times, Neurocrine is in a very, very good spot right now.

Neena Bitritto-Garg *Citi Investment Research – VP*

Great. No, that was that was great. And yeah, we're definitely going to try to touch on as many of those pieces of the story as we can in the next 40 minutes or so here.

So I just want to start off by talking a little bit about INGREZZA, of course. So on the second quarter earnings call, you know, the team kind of mentioned that there are a number of different dynamics at play in the third quarter. So there's seasonality, you know, in refills due to the summer months, inventory levels that we saw at the end of Q2, and then, of course, COVID-related concerns around just telemedicine versus, you know, promoting in-person. So I guess how should we think about the impact of each of those things on 3Q numbers?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah, myself and the rest of the team here, Matt and Todd and Eiry and Eric, and we've tried to be very transparent with everyone. And with that comes a lot of cautiousness that was picked up on our Q2 call. And there's several reasons for that. I'll start out with one that that you actually started out with is that, you know, our strongest quarters, if you look in a year, what are our strongest quarters for sales with INGREZZA? And it's Q2 and its Q4. Q1, which we've talked to death about, why that is a really challenging quarter because of the payor dynamics that take place in Q1, I think everyones well aware of. People do tend to forget the Q3, for reasons we don't totally understand at all, is also a very challenging quarter for us. It, you know, with the summer months and such that exists… not every year, we've had two out of the three years where Q3 was very challenging, one year it was not. So, like I say, for reasons that we don't understand but there's clearly a pattern in summer time. Then you come…have put that aside, then you come from how we've dealt with COVID…in Q2 is really when everything clamped down. Right?

And we then had to adapt as a company in being, in this virtual environment. When we did that, what we were mainly focused on, it's and I think many were focused on throughout the industry, it's you need to be able to focus on the patients you have. You have to put all your energy on all the patients who are on INGREZZA right now, make sure that their needs are being serviced. The great thing about INGREZZA is that the medicine itself is treating such an important condition. And the ability, the results that we've seen clinically and now in the marketplace are really astounding with the drug and physicians recognize that, patients certainly recognize that and value it. What we've talked about all along is that we've been able, we have a retention rate with patients that's pretty much unheard of. Not that we've said exactly what it is, but pretty much unheard of in this patient population. And so that's the very first focus…focus on the patients that you have and I think we did an excellent, excellent job of that in Q2. We then, as you move through Q2 and as we talked about on our call, we are a month into Q3, your attention starts then to say, OK, now it's continuing the education, bringing INGREZZA to more and more patients, which thinking about bringing more and more was never really an issue with us. This...it's just the education, working with the docs and the other health care professionals in the office… that takes care of itself because, as I said, huge unmet medical need, terrific drug.

In COVID it becomes it becomes much different. Things started to open up a little bit, then they contracted again in Q2, Q2 going into that first month of Q3. And we all kind of are living through that now, reopening yet again. What you do find that psychiatry has some real unique challenges with it is, psychiatry is, though, the specialty that is seeing fewer patients now per doctor than what they did pre COVID. And they're the ones that are utilizing telemedicine far more than the rest of the industry. And by and large, that means that those docs are not in their practices. But what we have adapted to, is opening back up as certain practices are. I would say now our sales group is about 50 / 50, being in the doctor's office and doing it via electronically. But, so that's not really where the challenges lie and where we're putting all of our energies, is not between Neurocrine representatives and the physician in their office, because by and large, even though 50 percent of our calls are into the office, the vast

majority of the time, 90, 90 percent or more of the time, the physician is not there. We're talking to the other staff at the offices.

It is being able to develop the tools now for the physician in order to be able to diagnose, recognize, diagnose tardive dyskinesia in an electronic environment. So that's what we've been spending most of our time now. New techniques, new technologies in order to then be able to keep our education going and to be able to allow the physician to become more confident in this electronic environment. It's kind of like taking that step back to the early stages of our launch, where we're giving the physician and their staff the tools to feel confident to recognize and diagnose when the patient is right in front of them. Now we're trying to do it electronically, and so that is a big challenge in the near term. The, over time, we're going to see that patients are going to be coming more and more into the office. Psychiatrists are going to be more and more in the office. But telemedicine is going to be a huge part of the psychiatric practice, probably forever now. So the investment in being able to diagnose a movement disorder via this kind of format and sometimes even telephonically…that's what we've got to do.

So what does that translate into, you know, the challenges as we talked about entering into Q3? It's just that. We're developing these things now. They don't all get developed all in the same day. They don't all roll out at the same time. And you're helping these physicians. They're seeing fewer patients. That's a downside. As we talked about, you have this environment to deal with. And in addition, the good side is they're spending more time with patients. So they're able to really see a lot better. So in that facial part of the of the disease, they're getting that. But it's in the rest of the extremities, they're not. There's a real big challenge in dealing with this. And then I'd say another challenge that and headwind that we have in Q3 is that we talked about, there was a pretty large inventory buildup at the at the end of Q2. And we said we're not sure how that's gonna to bleed out, how much is going to bleed out through Q3, but we thought quite a bit of it will be. And so there is that headwind. So when you when you look at this, we do suffer a bit like we do in Q1s, because we've grown our patient population that we're treating so much. So Q1 every year becomes a bigger and bigger challenge. Now, we've grown our patient population so much, and you have, well, we have great retention of patients, you do always lose patients… every week, every month, every quarter, every year, just like any drug. You lose patients. But that's a bigger, you know, numbers that you're losing. And in a COVID environment, you're trying to now replace them with the new patients that that are coming in. So that's a real challenge for the first time, is being able to replace all of those that you're losing and, you know, that's what we're dealing with. And so, it's short term. We're building the tools and everything, I think this is going to be actually a real big advantage for us going forward. I think telemedicine will actually be something that we're embracing and we think, as I said, there's going to be real advantages to telemedicine in our business and we're going to be taking advantage of those. We've already proven we're real good in the doctor's office and in that training. But there are still, what are we… diagnosis rate maybe 20 percent of TD patients at this point in time in the population? Is still how high will it go….Will it go 70, 80, 90 percent diagnosis? And even that 20 percent, only 50 percent of them are being treated with a VMAT2 molecule. So there's so much room for growth and it will grow in the intermediate and long term, it's going to be…it's…there's no question about this franchise, but it's the short term that we're dealing with and we're rising to meet the challenge. But there definitely are a lot of headwinds in Q3, there's no way to get around that.

Neena Bitritto-Garg *Citi Investment Research – VP*

Sure, no, that was that was a great over for sure and definitely understood. So, I guess just thinking about INGREZZA in Huntington's disease chorea, so you're also running the KINECT-HD Phase III study. So, could you just talk a little bit about just the benchmark for success there? There are obviously other VMAT2 inhibitors that are approved in that indication. So, if you could just talk a little bit about that and then kind of commercial implications as well.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah, so Huntington's is a natural indication for us to go in with this mechanism. We know the mechanism absolutely works in Huntington's. We have a single Phase III study. We started it up last year. This is in a highly vulnerable population, right? So it was one of the first studies we had to suspend.

And then nicely, as things have been opening up our centers and we're working with the Huntington's Study Group, which is the best group to be working with in performing these types of trials. We're open back up again and enrolling the patients again. There's, it's a very straightforward design, it's a UHPDRS that we're using here as the primary endpoint. And, you know, you have about 30,000 Huntington patients. About 90 percent of them have chorea associated with this. Only about 20 percent of them are being prescribed a VMAT2 inhibitor. And so there's a lot of room to grow VMAT2 within this population. And we think that several of the features that INGREZZA brings are key to growing that. These are patients….we don't have a box warning associated with the drug. It's a once a day drug. It's very simple to get a patient started on and maintained on. There's no titration involved with it. And, you know, these patients…we talk about once a day, we talk about those things…in this patient population that's actually important. They have a hard time swallowing. And sometimes they bite down and clench down on pills. That can be a very bad thing with other VMAT2 inhibitors, if you would happen to crush them inadvertently before swallowing the entire capsule. With ours, it really doesn't matter there. So, and we have clearly defined, you know, efficacy profile, at least in TD. And that's what we hope to show in Huntington's disease.

It's important both for the Huntington's patients, but also from our ability to grow our TD franchise. As you're aware, our main call point are psychiatrists in TD, about 80 percent of our calls are into psychiatrists, about 20 percent into neurologists. The neurologists we call on are all those same neurologists who treat Huntington's patients. Well, now we're going to be bringing them yet another, if you will, drug, but you're bringing them INGREZZA now approved for Huntington's. I would very much anticipate that bringing into their practices more value is going to raise the utilization of INGREZZA by neurologists in TD, not just in Huntington's so it's important to us for both of those reasons.

Neena Bitritto-Garg *Citi Investment Research – VP*

Absolutely. That makes a lot of sense. Great. So now I want to talk a little bit about opicapone or ONGENTYS now. You mentioned that it is going to be launched by the end of the quarter, so in the next couple of weeks here. So, could you just talk a little bit about, you know, kind of the status of the launch prep? And also just positioning, just given that there are other COMT inhibitors approved that are generic now. If you could just talk a little about positioning and how you think opicapone can kind of overcome some of the challenges that the other companies have faced.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Sure. And maybe for some of the viewers, just a tiny bit of background. Basically, when you have Parkinson's disease and as the disease progresses, you become less and less sensitive to levodopa. You start seeing more peaks and valleys to your blood levels of the levodopa that you're taking and levodopa is the gold standard. Unfortunately, we don't have any curative treatments for Parkinson's, knock on wood, you know, someday that's going to happen, but for right now, we just have symptomatic treatments.

What… no one just takes dopamine. From day one, when these, you know, there's about a million Parkinson's patients in the United States. 90 percent of them are on levodopa. No one takes dopamine because dopamine just on its own would cause way too many side effects that you have there, so you take it, you take levodopa with another compound that's always co-administered with it, which is an enzyme inhibitor, and it's called carbidopa. So you're taking levodopa and carbidopa simultaneously. And the reason for that is so that it inhibits the circulating enzyme, a decarboxylase, and so levodopa can make it into the brain. And that's where it can interact with the dopamine receptor.

There are two enzymes that break down, levodopa, and we're only inhibiting one of them. The other one is catechol-o-methyltransferase, COMT, and that's what ONGENTYS is. ONGENTYS is an enzyme inhibitor of COMT. So what we've been doing now in preparation for this launch for quite some time has been out there with our medical professionals, working with the Parkinson's community about educating them again, about COMT, that second enzyme that breaks down levodopa. You're already inhibiting one. You should be inhibiting both. And why is it that they need re-education on this? As you said, there's two other COMT inhibitors that exist and they've existed for about 13, 14 years now. Unfortunately, they were roundly disappointing when they were launched. One of them had

extreme toxicities, including death, had to be removed from the market, was put back onto the market with two black box warnings. That's not even worth a discussion of because it's rarely, if ever, used. The other one was put on the market shortly thereafter and obviously not great timing for that one to come out. But again, this one, which is called entacapone, was very weakly active and had to be given with each dose of levodopa. So being given four, six, eight times a day, adding tremendously to the pill burden. The point is, is that as these patients go through periods with their levodopa going high, but then they become dyskinetic, they have all those movements that they have to deal with. And then a few hours later, it goes back down into the right zone where they're not dyskinetic, they have normal movements. But then it goes down in a few hours where they start becoming slow and frozen. They take another levodopa and it goes through the cycle multiple times a day. Our COMT inhibitor, ONGENTYS, is given once a day, and it can smooth throughout the entire day, 24 hours, those cycles.

And so for the first time, you have a safe and effective COMT inhibitor, and it requires now us to do what I think we've shown we do really well with INGREZZA in tardive dyskinesia, is engage and educate the health care providers in, here is something really new and dramatic for them to bring to their patients. And success wouldn't be just replacing the existing COMT inhibitor in that patient population because still that's only a small fraction. There are other adjunctive treatments that they use before they go to COMT. Success is moving ONGENTYS way early into the treatment paradigm. So as the physician has their patient on levodopa / carbidopa and now that patient is starting to cycle more in the day, before they then say, OK, we're going to add another dose of levodopa / carbidopa… Let's use ONGENTYS and we can hold off on ever adding that other dose and then it makes it far easier on the patient and far easier for the physician to manage the patient. And that's what we'll call success.

And one last thing I would like to add on this. Again, who are the prescribing physicians? There's a movement disorder neurologist. We're already in all of their offices. So what we would see is is that now, we're going to, you know, in the very short near term, we're going to be bringing them INGREZZA for TD, INGREZZA for Huntington's, ONGENTYS for Parkinson's. That's a lot of value that you can bring to your, to a neurologist's office. And that again, should actually buoy INGREZZA sales is what we would look like also.

Neena Bitritto-Garg *Citi Investment Research – VP*

Absolutely. That also makes a lot of sense. Great.

So I want to talk a little bit about crinecerfont now moving to the pipeline. So the design of the Phase III study in adults with classical CAH was recently posted. So could you just walk us through, kind of the design at a high level and specifically kind of the choice of the primary endpoint, which is the reduction in glucocorticoid burden?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah. So, again, a little bit of background for those out there. This is a disease, CAH, which is congenital adrenal hyperplasia that a child is born with. And it's there their entire lifetime, it's a genetic disease. There's a mutation that they have in an enzyme such that you can't make cortisol. And up until the early 60s, all of those babies died shortly after birth because you need cortisol in order to live. But then hydrocortisone was invented. You could take that. So ideally, it would have been, can they just take a replacement amount so that you have physiological levels of cortisol? Unfortunately, no. Because it's an endocrine system that you're working with, with between the hypothalamus, the pituitary and the adrenals. And all endocrine systems work with feedback loops, positive and negative feedback loops. Because you don't have cortisol naturally occurring, you've…you not only missing that crucial molecule for life and health, you're also missing that negative feedback regulator in order to bring the system down, because now that you can't make cortisol, you're driving the androgens system wildly and from very tiny babies all the way through, if untreated, you'd have this massive androgen load that's taking place, which has a whole host of devastating health consequences to it. So here's a teeter totter you work with. You need to, you've got these huge amounts of androgens, you've got to bring them down. You giving cortisol at a physiological level that keeps them alive, but it does nothing to be able to regulate this. You have to give an amazing amount of cortisol, way supraphysiological to then bring down the androgens. But then having huge levels everyday of hydrocortisone has all sorts of serious deleterious health consequences. So then you have to teeter totter your patient. This is what the physician is constantly doing throughout life, is trying to keep changing that balance, trying to get it right. For

some periods of time, they can get it in to balance, but not very often, not for very long. It keeps teeter tottering, have to up and down, up and down your cortisol levels. There's not been another drug, other than cortisone from the early 60s, in order to treat these patients. What we have is a CRF antagonist, orally active, small molecule. And what that does is works at the adrenal and now brings those high androgens, now you're able to down regulate the androgens back to those normal levels. And that's what we showed in the phase IIb studies in adults and what we're doing now with the pediatric population in a phase II study. Drug was really well tolerated and really did a nice job of bringing down ACTH, 17-hydroxyprogestorone and androstenedione. So it did exactly what it had to do here. It now works as, let's say, maybe that negative feedback in order to capture the androgens. Well, that should mean that you can now lower that exogenous hydrocortisone you're taking and now bring it down to more lower normal physiological levels. Any lowering is going to be very good for the patient. But we want to see some really significant lowering of the hydrocortisone down so that now with these two drugs, you can come into balance and it's no longer a teeter totter that the physician is working with. And so that's really what we're doing. So we had, with the power of that phase II data that we had and the large safety database that we have with crinecerfont, we took that both to FDA and to EMA. And we had great discussions and really nice productive agreements that we had with both agencies. So now this is a worldwide trial that we're going, that we're doing. And the primary endpoint is going to be lowering exogenously added glucocorticoids. A key secondary is going to be what we've already shown in phase IIb is that lowering of the androgens. And so that is what we're doing in a single, pivotal study that we have ongoing. That's in the adults.

And as I said, we're now doing that same phase two study that we completed with the adults in pediatric population, and we're doing that stepwise like we did with the adults and engaging the agency on the pediatric pivotal study while we continue to run that trial. So what we want to be able to bring to this population of approximately 30,000 patients in the US, about the same number, a little larger over in Europe, is a medicine, the first one in 60 years for this patient population that will be…completely change, we believe, their life and certainly the management of this disease. And in addition, we've always been able, not always, Neurocrine has run global trials before, so that's not anything new to us to be able to run these in the United, a big single trial with many studies, many sites in the US and in Europe. Although I do have to say it's a challenge in this new environment, but it's one that we're dealing with. But then there comes the commercial side of it. And we have a clear presence commercially in the United States, so of course we will be, we will be commercializing this drug in the US by ourselves. But this is a very specific patient population with a real nice registry over in Europe. And so it is our intent that we're going to commercialize our, all on our own in Europe with crinecerfont too and build a worldwide presence with Neurocrine.

Neena Bitritto-Garg *Citi Investment Research – VP*

Great. So just one more question about the Phase III study. So in Phase II, we saw the Phase II results in adults earlier this year in June, patients had to stay on a stable dose of glucocorticoids. So just kind of curious how we should think about translating kind of the Phase II data into what we could see in Phase III based off of ACTH and androstenedione and, you know, some of the other, the biomarkers that we saw in Phase II.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah. So I think from a biomarker standpoint, we have great translatability from the Phase II over to the Phase III. I don't think that's, that's without question. We showed that in at least seventy five, or greater than seventy five percent of the patients, we lowered all of those steroid hormones by greater than 50 percent. So that aspect of it is very clear cut and translatability. They were on, we deliberately in Phase II, we didn't have them touch their exogenously added hydrocortisone. Here, that's what we're going to be tracking. And as I talked about, it makes sense. If this comes down, then you don't need to have this way up here and you can bring this down. We've not said exactly how that is going to happen or tracked. And there's a lot of creativity and years of work that went into how we made the design of this trial. So for competitive reasons, we are not disclosing that. But if, you know, from a scientific rationale and we, that's what we do believe is going to be attainable and that's what we've powered the study to be able to do this. And we've worked with some of the best CAH clinicians in the world in developing this study.

And the other thing I would say about the study is and the regulatory agencies were enthusiastically involved in this design. And that's key to making sure that the regulators really are actively involved and genuinely enthused about the medicines that that you're creating. But in such a design, you don't just work with the regulators. You also work with physicians. And as I said, we've brought in virtually all the KOL's throughout the world. But you also work with the patients and the patient advocacy groups to make sure that what they would look as valuable…What is the data that that we can generate here? Is this valuable to them also? Does this address their needs and the prescribing physicians, is this going to be that the label that we come up with? Is that going to really give them all the information that they want? And then finally, you work with payers and you engage them early on so that they understand, because they've not had to, they've not had to deal with any of this throughout the last 60 years. They've not had to deal with any new medicines for this patient population. And so you need to you need to be able to educate them on what you're doing with this medicine and the value that it brings. And so we're doing all of that.

Neena Bitritto-Garg *Citi Investment Research – VP*

Great. So now I want to talk about some of the earlier stage pipeline. So you recently announced a deal with Takeda for access to seven of their psychiatry assets. The most advanced asset is TAK-831. Now it has a very long numerical name, NBI-1065844. It's a D amino acid oxidase inhibitor. It's in Phase II for negative symptoms of schizophrenia.

So, at a high level, could you just talk a little bit about the strategic fit for these assets within the Neurocrine portfolio and a little bit about this lead asset as well, the mechanism and differentiation from some other similar drugs like sodium benzoate that have been in the clinic as well?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah. So you know the collaboration with Takeda is a really important one. And what I think many people who've maybe only followed Neurocrine for the last 10 years, just a brief history of time, don't recall that Neurocrine was founded as a neuropsychiatry company. And that's, we did multiple partnerships with J&J, Janssen, GlaxoSmithKline in anxiety and depression. Unfortunately, those, what we were investigating there, which was the CRF system in centrally, rather than peripherally, which we're doing now with CAH, where we were looking at it centrally for neuropsychiatric diseases. That, so neuropsych is something that we have never stopped working on in the labs. Number of different mechanisms that we've been working on. And so this has been a key focus of us for a long time.

It was really fortunate that when Takeda was looking at how were they going to deal with this new larger portfolio of drugs since their merger that they have, they didn't want to get out of neuropsychiatry, but how do they still retain the upside of it without having to expend all the resources because neuropsych takes a lot of resources. And that's when we began discussions with them. And we were able to reach, I think, a really nice deal that worked for both of us, which is basically a 50/50 cost and profit share where they get one time to come into it and one time to leave it depending on the asset that we're working on. So it, and then if they leave the 50/50, then they have it, it goes to a royalty. So it served all their needs that they had. They were still in it. They love their children here. We love their children too. And it serves our needs because it's multiple programs that we have with them. And the nice part about this is it helps reduce that risk for us. So the latest stage asset, as you said, is NBI-884, 844, and that is in the negative symptoms of schizophrenia. And as you know, we have the antipsychotics, first generations, second generations that, by and large do a very good job with the positive symptoms, but they don't touch the negative symptoms. There hasn't really been anything that really hits the negative symptoms well, and that is well tolerated either. And so with this, which is a DAAO inhibitor, it modulates the NMDA system, which, there is a wealth of evidence, both preclinical and clinically, that that's where the negative symptoms lie. And so that's what we are working on here. So that's what we're, that's what this drug is. It's in a big Phase IIb study that's international. And as we've directed, we would have this reading out next year and then if positive, we would then be working with the regulators. Neurocrine is in full control of these programs. And so, but we work hand in glove with Takeda as we move forward. But it's Neurocrine who does all the work and we share the costs.

Neena Bitritto-Garg *Citi Investment Research – VP*

OK, great. I know we only have a couple minutes here, so I just want to briefly ask about, you know, just kind high-level strategy. So, you know, as you mentioned, right, we've seen you do a number of in-licensing deals and product acquisitions over the last few years. So just kind of curious whether we should expect this sort of deal activity to continue, to change in any way in terms of kind of therapeutic area focus, deal size, things like that.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

There um, Neena, can I just ask one quick question, are we certain with our I.T. people on your side that this is, that there's no hiccups going on?

Neena Bitritto-Garg *Citi Investment Research – VP*

I haven't received, Todd did say to me that it looks like the link was not active, which did happen with one of the panels earlier today. Let me see. I haven't received anything on my end from…

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Because I just got (*inaudible*) from Matt our CFO shooting to me that….

Neena Bitritto-Garg *Citi Investment Research – VP*

There's nothing.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Well, he was just saying, I got that, you know, it's four minutes late, is there something wrong with the link? So that's why I asked.

Neena Bitritto-Garg *Citi Investment Research – VP*

OK, yeah, I can… I haven't gotten anything from our team. I can go ahead and, I don't know if the open exchange operators can, are you guys available to check?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

It's being recorded, so at least the recording would be online then if something has happened here.

Neena Bitritto-Garg *Citi Investment Research – VP*

Yeah. So I think, I haven't gotten anything from the conference organizers saying that there's any sort of an issue. I can reach out to them.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

But in that last couple of minutes, you did have a question. Could you throw it at me one more time and we'll close on that?

Neena Bitritto-Garg *Citi Investment Research – VP*

No worries, yeah, well, if it's being recorded then it's going to be posted later. It's fine. But yeah, it was just about, you know, we've seen over the last few years you've done a number of in-licensing deals and, you know, to grow the

portfolio. So just kind of curious if we should expect to see similar types of deals moving forward in terms of size and type or if I mean, could you consider a larger acquisition or kind of branching out into other therapeutic areas?

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Yeah. So, you know, basically what we're doing is we're investing in the company. We're investing internally in ourselves. We've had a highly productive R&D engine here. It's given us our three of our four approved drugs that we have. So that has proven itself and we are continuing to invest in that. But we understand that there's just amazing science that is being performed elsewhere. And as I said in my opening remarks, we're so well positioned to be able to form these types of partnerships.

So what we look for, the first, the first two things we look for are great science and that the mechanism that is being explored is going to have a really meaningful impact and a real game changer for the patients and the physicians who are serving those patients. That's the first two things, that's our guiding principles.

And how do we focus ourselves? Well, we're a neuroscience company, but neuroscience is a big area. There's neurology, which let's say TD certainly, certainly is in there, which Parkinson's is certainly there. There's neuroendocrinology, which is ORILISSA and ORIAHNN and crinecerfont. So we are very much in neuroendocrinology. There's neuropsychiatry. And now, as we just discussed and we only, we only talked about one of the multiple assets that we have with Takeda to have multiple assets now in neuropsychiatry. I'd say probably the only pillar that that is left unexplored by us right now, but is certainly one that we're very interested in internally, is neuroimmunology.

And so what you and what you also see with our collaborations is that it really spans mechanisms also. We move from, which will always be there, symptomatic treatment of devastating diseases, to, with Voyager, gene therapies in order to treat diseases and potentially even be curative. And then going into with small molecules, really digging down and going to the core of the mechanism of the disease, even with a small molecule, as we have done in our epilepsy programs. And so those, we are agnostic about the, what the actual medicine is going to be. Like I said, it has to just serve a huge medical need and the science has to be superb. And then what you work to do is you work to find a financial structure that works for both parties. And thus far, I think we've done some really unique financial structures. Could those in the future continue to replicate those? Certainly. Could there ones that are going to be different from those? Certainly. We just look that each party is getting the correct value.

Neena Bitritto-Garg *Citi Investment Research – VP*

Excellent. That makes a lot of sense. All right, I think we are out of time.

I will go check on the tech issue, but I really appreciate you taking the time to speak with me today.

It's been very, very helpful. Very insightful. Thank you again.

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Thank you, Neena. Take care

Neena Bitritto-Garg *Citi Investment Research – VP*

You too. Thanks

Kevin C. Gorman *Neurocrine Biosciences, Inc. – CEO & Director*

Bye-Bye

Neena Bitritto-Garg *Citi Investment Research – VP*

Bye