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): February 4, 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 2.02. Results of Operations and Financial Condition.

On February 4, 2020, Neurocrine Biosciences, Inc. (the "Company") held a live conference call and webcast to discuss, among other things, the Company's financial results for the fourth quarter and year ended December 31, 2019. 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, Current Reports on Form 8-K, 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 disclaims any 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.

Exhibit	Description
99.1	Transcript of the Neurocrine Biosciences, Inc. conference call on February 4, 2020
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibit 101)

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.

Date: February 5, 2020

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

CORPORATE PARTICIPANTS

Eiry Wyn Roberts *Neurocrine Biosciences, Inc. - Chief Medical Officer* **Eric S. Benevich** *Neurocrine Biosciences, Inc. - Chief Commercial Officer* **Kevin C. Gorman** *Neurocrine Biosciences, Inc. - CEO & Director*
Kyle W. Gano *Neurocrine Biosciences, Inc. - Chief Business Development and Strategy Officer*

Matthew C. Abernethy *Neurocrine Biosciences, Inc. - CFO*

Todd Tushla *Neurocrine Biosciences, Inc. - VP of IR*

CONFERENCE CALL PARTICIPANTS

Brian Peter Skorney *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

Charles Cliff Duncan *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

David A. Amsellem *Piper Sandler & Co., Research Division - MD and Senior Research Analyst* **Evan David Seigerman** *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst* **Jay Olson** *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst* **Joseph Robert Stringer** *Needham & Company, LLC, Research Division - Associate*
Kyuwon Choi *Goldman Sachs Group Inc., Research Division - Equity Analyst*

Laura Christianson *Cowen and Company, LLC, Research Division - Research Associate*

Marc Harold Goodman *SVB Leerink LLC, Research Division - MD of Neuroscience & Senior Research Analyst*

Owen J. Drinkwater *RBC Capital Markets, Research Division - Associate*

Paul Andrew Matteis **Stifel, Nicolaus & Company, Incorporated, Research Division - Co-Head of the Biotech Team, MD & Senior Analyst**

Tazeen Ahmad *BofA Merrill Lynch, Research Division - VP*

Tessa Thomas Romero **JP Morgan Chase & Co, Research Division - Associate**

PRESENTATION

Operator

Good day, everyone, and welcome to the Neurocrine Biosciences Fourth quarter and Year-end 2019 Results Call. (Operator Instructions) Please note, today's call will be recorded. (Operator Instructions)

It is now my pleasure to turn the program over to Kevin Gorman, CEO of Neurocrine Biosciences. Please go ahead.

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

Thank you very much, operator. And thank you, everyone, for joining us here this afternoon. Today, I have Eiry Roberts, our Chief Medical Officer; Eric Benevich, Chief Commercial Officer; Matt Abernethy, CFO; Kyle Gano, our Head of BD and Strategy; and Todd Tushla, our Head of IR, with me.

Before we start out, Todd, could you read our safe harbor statement.

Todd Tushla - *Neurocrine Biosciences, Inc. - VP of IR*

Yes. Good afternoon, everyone. Certain statements made in the course of this conference call that are not historical statements to 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 third quarter 2019 Form 10-Q 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 C. Gorman - *Neurocrine Biosciences, Inc. - CEO & Director*

Thank you, Todd. I'm going to keep my remarks brief so we can get to your questions. First and foremost, 2019 was a year where we continued to make progress in our primary focus of educating healthcare providers, caregivers and patients about tardive dyskinesia. These efforts will continue in 2020 and beyond, because the vast majority of tardive dyskinesia sufferers are still struggling, while waiting for a diagnosis and for appropriate treatment. We believe 2020 will be another year of significant growth for INGREZZA.

Now having said that, we're fortunate not to be a single-product company. In 2009, we also took important steps to build the leading neuroscience biopharmaceutical company by nearly doubling our pipeline of important medicines. This year, we will have 3 compounds in pivotal clinical trials, 5 compounds in Phase II studies and the real possibility of having 3 medicines approved in 4 indications.

Now that's a powerful foundation from which we'll build. With that said, I'd like to turn the call over to Matt and Eiry.

Matthew C. Abernethy - *Neurocrine Biosciences, Inc. - CFO*

Good afternoon, and thank you for joining our fourth quarter earnings conference call. I will keep my comments brief since we provided a lot of information over the past month.

Overall, INGREZZA demonstrated another strong quarter with $238 million in net product sales, putting sales over $750 million in 2019, just our second full calendar year on the market. Given our increased business development activity and noncash P&L items, we will begin reporting our financial performance on a GAAP and non-GAAP basis. Full reconciliations are included in the tables of our press release.

Our sales results translated into increasing profit with Q4 net income of $34 million and non-GAAP net income of $102 million. For the full year 2019, we finished with net income of $37 million and non-GAAP net income of $284 million. We exited the year with $970 million in cash and marketable securities.

Regarding 2020 SG&A and R&D expense guidance, we expect a range of $740 million to $770 million on a GAAP basis, and $620 million to $650 million on a non-GAAP basis. This compares to $469 million of non-GAAP R&D and SG&A expenses in 2019. The increase for 2020 reflects our increased investment in R&D, including our 3 registrational programs and meaningful investments in our Voyager and Xenon collaboration.

For SG&A, our guidance reflects continued investment in INGREZZA and marketing costs associated with the anticipated launch of opicapone. Please note that our GAAP guidance reflects approximately $100 million of share-based compensation and a $20 million expected milestone payment to BIAL connected with the expected approval of opicapone by the FDA during the second quarter.

No other future potential milestones or IP R&D associated with current collaborations or future business development activities are included in our GAAP guidance.

Regarding INGREZZA, while we've made tremendous progress developing the tardive dyskinesia market, diagnosis rates for TD are still only in the mid-teens. We'll continue our educational efforts to remain confident in our ability to help many more patients struggling with TD. Healthcare providers, patients and insurers continue to understand the value of INGREZZA, and we expect access will remain strong with similar net revenue per script in 2020 as what was realized in 2019.

As we think about Q1, the first quarter of every year is challenging for any company with a specialty tier drug due to payer-related seasonal dynamics. We are working diligently to mitigate the impact from these headwinds. Although the first quarter poses unique seasonal challenges, our long-term focus is ensuring new patients receive help with their TD and existing patients stay on INGREZZA throughout the year.

Overall, 2020 signifies an important year of increased investment into Neurocrine as we continue to grow INGREZZA, advance our existing programs and expand our pipeline.

With that, I'll now hand the call over to our Chief Medical Officer, Eiry Roberts.

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Thank you, Matt, and good afternoon to everyone on the call. I will also keep my comments brief today. We remain on track with all clinical program timelines across the portfolio, including the anticipated midyear start of the registrational trial for crinecerfont in adult patients with congenital adrenal hyperplasia. Ahead of this, we will present the adult proof-of-concept data for crinecerfont at the ENDO meeting in San Francisco on March 30.

By the end of this year, we plan to have a diversified portfolio of multi-stage programs in clinical development at Neurocrine, including 3 registration study stage studies, each in a different clinical indication; and 4, early- to mid-phase neurocrine clinical program.

In the near term, the most important program in the Neurocrine clinical portfolio for patients is opicapone with a PDUFA date of April 26. Opicapone has the potential to significantly help patients impacted by motor fluctuations in Parkinson's disease, who need better adjunctive treatment options. We look forward to bringing opicapone to patients in the U.S. and to educating physicians, patients and payers on the impact, that this well tolerated, differentiated COMT inhibitor can have an improving motor functioning for Parkinson's patients.

For my remaining remarks, I'll review our 2 most recently announced collaborations, which highlight Neurocrine's entry into the field of precision medicine through our focus on rare pediatric epilepsies.

Firstly, in December, we announced an important collaboration with Xenon Pharmaceuticals, gaining exclusive rights to NBI-921352, a promising first-in-class molecule, which potently and selectively inhibit the Nav 1.6 sodium channel. We believe this molecule could have great promise in the treatment for SCN8A developmental encephalopathy or 8A for short, a rare and devastating type of pediatric epilepsy specifically related to a gain of function genetic mutation of the Nav 1.6 sodium channel. 8A very often presents in the first few months of life, and causes a chronic and complex seizure disorder with developmental delays. In addition, sudden unexpected death can occur in 10% to 20% of patients with 8A.

For the first time, with NBI-921352 and its selective mechanism of action, we plan to precisely target the ion channel implicated in 8A and offer the opportunity to provide a significantly improved benefit risk profile for these patients relative to currently available treatments.

Beyond 8A, NBI-921352 also has great potential in a range of seizure disorders, including adult focal epilepsy. We plan to file an IND application for this molecule with the FDA in the middle of 2020 in order to start a Phase II trial in a 8A patient in the second half of this year.

Secondly, in January, we disclosed that we had entered into an agreement with Idorsia, which includes the option to exclusively license ACT-709478, a potent, selective, orally-active and brain penetrant T-type calcium channel blocker, which has completed Phase I clinical study as a potential treatment for rare pediatric epilepsy.

Pending approval of the IND later this year, we plan to initiate a Phase II study in a rare pediatric epilepsy starting in the second half of this year.

In addition to the treatment of epilepsy, this mechanism has potential application across a broad range of important neurological disorders, including essential tremor and pain.

Our collaborations with Idorsia and Xenon are not competitive. In fact, they are highly complementary and reinforce our commitment to addressing the needs of patients born with rare and devastating forms of epilepsy for whom currently available treatment options are largely inadequate.

It is our expectation to have these 2 molecules in Phase II in rare pediatric epilepsies by the end of this year. Through our internal research efforts and through collaboration agreements with Xenon, Idorsia and our gene therapy programs with Voyager, we've nearly doubled Neurocrine's pipeline over the last 12 months. Each program, our growing pipeline has the potential to make a dramatic impact on the lives of patients and their families.

And I'd like to close by thanking the many cross-functional teams at Neurocrine and at our partner companies for their hard work to advance these important molecules. Kevin?

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

Thank you, Eiry. So we're ready to take your questions at this time.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll take our first question of the day from Tazeen Ahmad with Bank of America.

Tazeen Ahmad - *BofA Merrill Lynch, Research Division - VP*

Maybe Eiry, a question for you. You made it a point to say that the programs that you're partnered with Idorsia and Xenon are not competitive with each other. When do you think you would be in a position to talk about what specific indications you would be pursuing for -- for one or both of these programs?

And also, how you're thinking about the general epilepsy space as those seem to be getting crowded with various mechanisms of action of drugs that are being investigated?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Thanks very much for that. So first of all, I mean, obviously, many of the drugs that are currently used in the epilepsy space, particularly in the broader, more generalized epilepsies are actually very old and in fact, in terms of their benefit risk profile, we believe there is a significant opportunity still to serve patients in that broad epilepsy environment.

If we think about the 2 mechanisms that we're focused on here. Although sodium channel blockade and calcium channel blockade have been the mainstay of treatment in epilepsy over the long-standing path. Our sodium channel approach here with the Xenon collaboration gives us the opportunity to target very specifically, one of the sodium channels through Nav 1.6. And in doing that, we believe we have the opportunity to much more selectively and on a precise way address the symptoms of epilepsy, first obviously, in the rare SCN8A pediatric epilepsy. But beyond that, more broadly, in adult focal epilepsy.

With respect to the other collaboration with Idorsia, obviously, we are still in the option phase of that agreement and once we have the opportunity to talk more about that as the IND is approved, then we'll be able to say more about the potential indication for that collaboration.

Operator

And we'll go next to Paul Matteis with Stifel.

Paul Andrew Matteis - *Stifel, Nicolaus & Company, Incorporated, Research Division - Co-Head of the Biotech Team, MD & Senior Analyst*

Just 2 on INGREZZA. I was wondering if you could comment a little bit on what you're seeing with respect to contracting? What do you foresee for this year? In the past, you talked about certain plans, picking one of the INGREZZA (inaudible) is preferred, but that not being rate-limiting for getting INGREZZA access. Maybe you could just speak that dynamic is continuing?

And then second, as it relates to [1.2] with seasonality being a player this quarter and then also a potential $11 million inventory headwind, is there a risk that we could actually see a sequentially down quarter? How are you thinking about that? Is that inventory going to [flow out] all at once or maybe over time?

Matthew C. Abernethy - *Neurocrine Biosciences, Inc. - CFO*

Yes, Paul, we'll take those questions sort of in reverse order. So as we think about the first quarter, to your point, what we reported in Q4 was $238 million in net product sales that included in it an $11 million inventory build. So the right jump-off point for Q4 would be $227 million.

Now as you think about how that translates to Q1, there's really 3 dynamics at play, but that we would want to make sure everybody thinks about informing consensus and expectations for Q1. The first 1 being the gross to net discount. Q1 is always our largest gross to net discount period because of Medicare Part D Medicare Part D donut hole and commercial copay assistance. And as you think about what I said last year, many people have estimated the impact of that could be between 4% and 5% sequentially as you think about Q4 versus Q1. So I think that's probably a directional number.

The second piece, which is actually the most material piece has to do with the delays that occur at the beginning of each year as patients go through a reauthorization process with their existing plans. And what occurs in that is it's just an extended cycle time for a patient to get their first fill and ultimately leads to a lower refill rate per patient.

Now the rate may be very similar this year as compared to last year, but the dollar magnitude will be significantly greater because we've actually doubled the number of patients on INGREZZA as -- if you compare the time now to last year. And just by way of illustration, if you -- and just to frame out the quantification is that if, on average, a patient had a reduction of 0.25 scripts within the first quarter, that would have a sequential headwind of between 4,000 and 5,000 TRx. So it could be a meaningful impact. It's not unique to us, this happens to many that have -- our specialty tier medicines. And it is clearly not a reflection of the underlying demand for INGREZZA, it's purely just a fulfillment challenge that you work through, and the teams are working hard through right now.

And then the third item is the inventory bleed that you just brought up. We have that $11 million build, it's hard to predict [how] that will materialize in the first quarter, but it's surely something that should be on your radar as far as setting expectations. And I'd just say, although I'm highlighting all these Q1 dynamics, the real emphasis here is just to make sure people understand and set appropriate expectations for the first quarter, but it does not reflect our long-term belief in the opportunity that we have within 2020 to help many more patients with INGREZZA. We're in the mid-teens of diagnosis with a fraction of that actually receiving treatment. We have a lot of opportunity ahead of us, but very complicated but we're working through this Q1 dynamic, and we wanted to make sure we provided adequate color. Anything else, Eric?

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

Yes. Paul, if I remember correctly, the first part of your question was really related to contracting activity and sort of expectations for coverage in 2020. So I'll start off by saying that patient access is critically important for us. And throughout the course of the launch, we've invested significantly

in making sure that patients and providers have relatively open access to INGREZZA. This is a specialty medication, virtually all the prescriptions require prior authorization through the plan before those claims are approved and the patient can initiate treatment.

But we've really been very pleased with the success that we've had through the early days of the launch and all the way up to current times, with over 70% of written prescriptions being filled. And from an affordability perspective, 3 quarters of patients paying less than $10 per month for fill.

So in the more recent phase of the launch, we started to gather more attention from payers as INGREZZA has become a larger brand. And certainly, we've said previously that we started to engage selectively with plans in terms of contracting activity. And I will reemphasize the word selectively because over the course of the launch, we found that regardless of whether we are on formulary or not on formulary. We've been successful in securing approval or helping to secure approval for patients in need of INGREZZA.

So where we stand today is that we're approximately a month into the quarter and a month into the year. We feel good about what the coverage landscape looks like for INGREZZA. We expect the access to remain strong in 2020. And as Matt said in his prepared remarks, we expect the net revenue per script in 2020 to be similar to what it was in 2019 as well.

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

And about the only thing that I would like to add to what Matt and Eric have said, is that the good news is that we start 2020 with nearly twice as many patients as we started 2019, and that's great. It shows the acceptance of INGREZZA in the patient population and also by our customers, the Allied Health professionals. But the downside of that is, as we've talked about, it leads to the challenge in Q1. And you have seen in the past and as we talked about before, that it's an ebb and flow. So Q1 is the ebb and Q2 generally is the flow as we come out of it and we have a strong year. So that is -- we just wanted to be able to give as much color to this quarter and to the year as we could on this call.

Operator

Next, we'll go to Brian Skorney with Baird.

Brian Peter Skorney - *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

I guess maybe if I can ask about ACT-709478 program. Can you just kind of walk us through your thoughts on the development program, how you envision this drug being used? And maybe your thoughts on clinical trial design and mechanism? How you can overcome some of the difficulties, others have had in developing recent drugs and epileptic indications, specifically thinking about kind of the recent neurosteroids that are primarily GABAergic, but also do block T-type calcium channels? And would you envision this Phase II study being placebo-controlled or a comparator study?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Thanks for the question, Brian. So I think just as an initial statement with respect to the mechanism of action of the Idorsia molecule, this is a very highly potent and very brain penetrant calcium channel antagonist. And we believe that those calcium channel antagonists that have been used in the past and quite extensively form the mainstay of epilepsy treatment, really haven't been able to fulfill the promise of that mechanism, because of their low potency. And the relationship that has to the inability to dose the doses that can produce the required efficacy without side effect issues. In many cases, off-target side effect challenges as well. And so in terms of that alone, we believe there is a significant opportunity to demonstrate value through this mechanism in the field of epilepsy.

I can't really comment on the development plan for this molecule specifically. As I mentioned earlier, we're still in the option phase with this collaboration. And -- but we are very excited about the opportunity to move forward in this space. And we hope that as the IND becomes approved later this year that we'll be able to say a lot more about our intention to move this molecule forward in the space of initially rare pediatric epilepsy, but subsequently, more broadly in other areas such as those I mentioned earlier, essential tremor and potentially pain.

Operator

And next, we'll go to Brian Abrahams with RBC Capital Markets.

Owen J. Drinkwater - *RBC Capital Markets, Research Division - Associate*

This is Owen on for Brian. So 2 for me. First, on the CAH program, I know the data is coming in March. Just wondering if you could give a little more color on maybe what we should expect to see there? Whether you'll report sort of patient-by-patient or whether you'll have a responder analysis versus absolute reductions in the biomarkers?

And then second one actually on opicapone, just wondering about how the familiarity is with the U.S. physician population, given that the drug has been approved in Europe, and maybe there's some crosstalk there. Just general familiarity with the drug and the approach that could potentially drive the launch?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Well, thanks, Owen. First with CAH, and we will be reporting the data from all 4 cohorts of the adult proof-of-concept study. As I think we've mentioned before, the design of that study was an adaptive study, which allowed us to look at optimizing both dose and dosing schedule for the CAH program in molecule crinecerfont in adults.

In terms of the type of data we will be presenting, obviously, that is a 14-day treatment, proof-of-concept study. So we will be presenting both summary and individual data around the biomarkers measured and several different approaches to the analysis of those data. As I think I mentioned earlier, that presentation will be an oral presentation on March 30 in San Francisco at the ENDO the thing.

Beyond that, we're very pleased with where we are with the CAH program, both in adults and in pediatrics. Clarity on the adult registrational path forward at the end of last year from agencies both in the U.S. and Europe. And we're moving ahead to implement the adult registration trial, which will be a global trial, starting in the middle of this year, and we continue to make progress with the pediatric program as well.

With respect to opicapone, our medical affairs organization in preparation for the upcoming PDUFA date in April, has been working hard with the neurology community to help educate around the role of COMT. We believe that there has been a little opportunity to deliver on the promise of COMT with the currently available COMT inhibitors that are available in the U.S. right now. And so as we interact with neurologists, we hear excitement from those prescribers about the opportunity to bring forward another potential option for their patients with motor fluctuation.

In particular, we are very encouraged by the profile that we see for opicapone. It's a very straightforward, once-a-day treatment with an extensive clinical trial program that demonstrated a really favorable benefit-risk profile. And we are very much looking forward to bringing that forward for patients in the United States.

Operator

And next, we'll go to Anupam Rama with JPMorgan.

Tessa Thomas Romero - *JP Morgan Chase & Co, Research Division - Associate*

Great. Good afternoon. This is Tessa on the call today for Anupam. Maybe one from us on the KINECT-HD study in Huntington's disease. Perhaps you might review for us any gating factors to initiating in that study. I think that guidance there is the first half of this year and then maybe you might comment on overall rationale to pursue this indication given competition in the space?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Thanks so much, Tessa, it's Eiry here. First of all, just a clarification, we actually did initiate the KINECT-HD study at the end of last year in November. And just as a reminder, that is a Phase III, placebo-controlled study of 120 subjects with Korea in Huntington's disease, comparing valbenazine to placebo in that population. And we anticipate that, that study of 120 subjects will be enrolled over this year and that we will have data sometime in 2021.

And the -- with respect to -- can you remind me the second part of your question, Tessa, sorry.

Tessa Thomas Romero - *JP Morgan Chase & Co, Research Division - Associate*

Yes. Sorry, I may not come too clearly, realizing that the study is initiating -- has initiated right? I'm wondering overall rationale in the indication given overall competition? And then maybe how you're thinking about differentiation relative to TEVA's AUSTEDO -- AUSTEDO within the same indication?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Okay, okay. Oh, that's fine. So there are 30,000 patients in the United States with Huntington's disease. Of that population, about 80% to 90% of them troublesome chorea. But even though the VMAT2 mechanism has been proven in that patient population, there's still only about 20% of those patients with chorea that receive treatment with a VMAT2 inhibitor and so from that perspective, we believe there's a significant opportunity left to serve these patients and what we're particularly interested in is the profile that we have of valbenazine, with its once-a-day treatment, simple titration and favorable better risk profile.

Operator

And we'll take our next question from Jay Olson with Oppenheimer.

Jay Olson - *Oppenheimer & Co. Inc., Research Division - Executive Director & Senior Analyst*

And congrats on all the business development activity in 2019. I was wondering if you could comment on your plans for BD in 2020? Should we expect you to do some more of the types of deals that you did last year? And then separately, any comments you could make on the time line for the collaboration with Voyager on Parkinson's disease gene therapy, what are the next data readouts there? And how you see the competition shaping up?

Kyle W. Gano - *Neurocrine Biosciences, Inc. - Chief Business Development and Strategy Officer*

This is Kyle. Thanks for the question. On the BD front, right now, there's a lot of great science going on outside the doors here of Neurocrine, and we appreciate that. And considering our long-term goal here is to be a leading neuroscience company and a global one with studies and products in various markets. It's our goal here at Neurocrine to invest both internally and externally. So we'll continue to look for projects that are aligned with our strategic thoughts and goals and objectives here. And if we find a good fit, we'll look at bringing the project in-house.

So I think that the parting word here is we continue to be active in business development and looking to bring new programs into the companies if they make sense.

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

On the Voyager collaboration, we had interactions with the agency towards the end of last year, which gave us good clarity on the registration program for Parkinson's disease. We got clarity on the RESTORE-1 trial and how we could ensure that, that was viewed as a registration quality study. That involves an amendment to that protocol, and we're moving forward with implementing the amended RESTORE-1 protocol right now.

In parallel, we're also starting up RESTORE-2, the second pivotal trial, that will be a global trial and will be starting later this year.

The only thing I'll add, actually, is we will be releasing the 36-month data from the PD-1101 study, which was the dose-finding study at AAN this year.

Operator

And next, we'll go to Laura Christianson with Cowen.

Laura Christianson - *Cowen and Company, LLC, Research Division - Research Associate*

I guess, going back to CAH. I'm curious if ENDO data that you're planning on presenting in March will include an analysis comparable to what we can expect in the registrational trial, whether you'll be looking at the same primary endpoint planned for that trial?

And then secondly, in your interactions with the FDA, you have a sense of how important it is to show that the drug allows for a reduction in steroids? And if that will be part of the alternative dosing regimen, one of the cohorts that will be presented?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Well, initially, the proof-of-concept study is a 2-week study, dosing in adult subject. And the outcomes looked at in that exploratory study where the hormone biomarker levels. And so that's what we will be presenting together with, obviously, the full tolerability profile at the ENDO meeting.

With respect to the endpoints for the registration trial, we haven't commented to any great extent on that. As soon as the trial will actually is up and running, we will post that on clinicaltrials.gov. And obviously, that will include a full description of the study design and the sample size and also the endpoints that we're looking at.

It's clear, though, that the steroid hormone levels [Technical Difficulty] sort of how this disease is managed and how patients could be impacted by a novel treatment and so that will be a core part of the program moving forward. It's also very important to us that we understand steroid dosing in the context of use of this new novel nonsteroid mechanism.

Operator

Next, we'll go to Charles Duncan with Cantor Fitzgerald.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

And congratulations on a very good year of INGREZZA growth. My first question is related to continued INGREZZA growth and not to be overly simplistic, but I'm wondering if you could point to just one key driver that you would highlight as important to you executing your business plan this year to drive INGREZZA growth? Would it be additional or increased diagnosis, additional penetration in new or existing prescribers or such as pricing change? What is the one thing that you want to see happen this year?

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

Charles, this is Eric. I'll actually give you two. We mentioned earlier, the payer dynamics in Q1 and the fact that we've got a plan in place to mitigate the impact of all these patients that require a reauthorization or patients that are switching plans et cetera, et cetera. So one of the priorities for our team is to make sure that we're executing against that plan, minimize the impact that all these -- beginning of the year, payer dynamics can have on disrupting treatment and make sure that we're really focused on executing that as well as driving new patient starts in Q1.

You may recall that last year, Q1 was really a tale of 2 half quarters. The first half of Q1 was a strong focus on making sure that any patients that were experiencing treatment lapses were able to get back on treatment. Second half of the quarter, we saw a real surge in new patient starts. And so we want to make sure that we're executing against our plan in Q1 and setting ourselves up nicely for the rest of the year.

And then, as Matt mentioned earlier, as yet, almost 3 years into this launch, the vast majority of patients with tardive dyskinesia, have yet to be diagnosed. We think that diagnosis rates are in the mid- to high teens. So that means over 80% of people out there that have TD haven't been given a diagnosis and haven't been offered treatment for it. So the focus has been and will remain for quite some time. To bridge that gap between the undiagnosed patient population and the prevalent population. And so we're going to continue to focus on disease recognition, helping to improve the diagnostic acumen of the prescribers that are out there. We've also been investing in helping patients to recognize when they're experiencing TD symptoms. Or what may be TD and encouraging them to have a conversation with their doctor. And as you're probably aware, one of the big ticket items in our plan this year -- last year and into this year has been our unbranded DTC disease awareness campaign called talk about TD.

So we're going to continue to execute on our plan. We're continuing to educate providers on what is TD and what isn't TD, the benefits of INGREZZA, how quickly it works and the reductions of involuntary movements that are seen in our clinical data. But getting a good start in Q1, mitigating the impact of the payer disruption and then continuing to raise awareness in driving diagnosis of TD are going to be key for us in 2020.

Charles Cliff Duncan - *Cantor Fitzgerald & Co., Research Division - Senior Analyst*

Perfect. That's helpful. Eric, appreciate the added color. One quick question on opicapone, when you look at the opportunity set there, is it one that will be measured by initial prescriptions for opicapone and the PD community or increase [mind] share within the neurology community?

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

Sure. Eiry had commented a little bit earlier about the receptivity that we've seen thus far here in our preparation for a planned launch later this year. I will say that given the established treatment options, it's going to take time for us to remind people about the role of COMT in optimizing levodopa therapy. This is a little bit of an unusual dynamic in that, all the clinical studies, and therefore, all the clinical experience thus far is outside of the U.S.

So for the average neurologist or community physician that's treating Parkinson's patients, they may not be aware or that familiar with opicapone. I will say, though, that key opinion leaders, thought leaders in movement disorders, specifically Parkinson's are generally familiar with the data and are enthusiastic about having this new treatment option available to them on the other side of an FDA approval.

So we're doing the work to prepare now for an eventual launch later this year. Certainly, as Eiry mentioned, the medical organization has started that process of reminding people about the important role of COMT in optimizing levodopa treatment. And as you may recall, when we expanded our field sales team towards the end of 2018, and it was with dual goals in mind to optimize the team for the TD opportunity, but also to prepare for the eventual launch in Parkinson's disease.

So we've got our team in place. We cover all of the movement disorder specialists that are out there. And as we progress towards the launch, we're going to be doing additional things like training our team on disease data and so on, so that we can be well prepared to launch after we get FDA approval.

Operator

Next, we'll go to Paul Choi with Goldman Sachs.

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

I had 2 questions on for crinecerfont for CAH. First, just on the pivotal trial design. Could you maybe just clarify for us whether you -- this trial can be used for global registrational purposes? And if you'll have European sites on board, I think in the past, you've talked about this being your potential foray to becoming a global company and selling it in Europe, and Eiry and Kevin, if you can comment on that?

And the second question I have is just also on CAH with regard to the pediatric Phase II that's ongoing. I didn't see it in the slides, but is the plan still to top line those results later this year? And could you maybe speak to the development path in the pediatric population and whether you intend to pursue it in younger patients as well?

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

Yes. Thanks, Paul. You are correct in your recollection that this adult Phase III study, we look at as a global registration study. We've been in contact with both the European Regulatory Agencies as well as the FDA. And so that is what we're doing a little later this year as being able to do that with sites all throughout Europe and the United States.

And it will be a situation that we have reached the level in the company of sophistication and resources that we can commercialize this ourselves over in Europe. So we would not be seeking a partner there, and that would be our first foray into becoming a global pharmaceutical company.

And Eiry, you want to talk about the second half of Paul's question.

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Yes. So with respect to the pediatric program, the proof-of-concept study is obviously the first step in that regard, and we continue to make progress with that. That is an adaptive trial similar to our previous adult proof-of-concept study. In parallel with that ongoing study though, we are engaging with the regulators both in the U.S. and Europe right now to determine the registration trial design for the pediatric indication, which will also be a global program. And so as we go through this year and we gain more clarity on that, we can certainly provide more information.

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

And is the plan to go into younger patients as well versus the sort of teenagers that are currently being studied in the Phase II?

Eiry Wyn Roberts - *Neurocrine Biosciences, Inc. - Chief Medical Officer*

Yes. That is the plan.

Operator

Next, we'll go to Evan Seigerman with Crédit Suisse.

Evan David Seigerman - *Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst*

It was great to see you a couple of weeks ago in San Francisco. One specific question, so when you think about the net -- or the price increase that you had mentioned, how much of that do you expect to get on a net basis?

And then my second question is, just on a high level, what opportunity or opportunities do you see in your pipeline and portfolio that could be as significant and impactful as INGREZZA?

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

Well, I'll take the second one, Evan. I think there are several compounds that we have there that can be as impactful and even more impactful to patients because of the devastating effects of these pediatric epilepsies that we see. These children -- these babies need these medications like right now. We have a tremendous sense of urgency in going forward -- in going forward with those.

Also within CAH, there's been nothing for these patients for decades now. And again, the impact that could be seen there. But at the end of the day, I would say that it sounds trite, but we wouldn't work on a clinical program or a preclinical program for a research molecule or mechanism unless we thought that there was a real impact that is going to be there.

And so with everything that we're working to bring to market right now, whether you talk about opicapone, whether you talk about Huntington's, whether you talk about uterine fibroids, and I know that, that's our partner that's bringing that forward, but there's millions of women suffering from that. And as I said, these rare pediatric diseases, our work with Voyager on the programs that we have going on there. This is all something we don't prioritize in rank here at Neurocrine. And we think that they all deserve our attention.

Matthew C. Abernethy - *Neurocrine Biosciences, Inc. - CFO*

Evan, this is Matt. So on the net pricing front, if you recall, we took a price increase in the middle of November. And we've not disclosed exactly how much of that sticks, but I would just tell you, a large majority of that flows through, but it's not at 100%. So you would get about half a quarter's benefit of that price increase in the first quarter.

Operator

And we'll go next to David Amsellem with Piper Jaffray.

David A. Amsellem - *Piper Sandler & Co., Research Division - MD and Senior Research Analyst*

So just a couple. First, on INGREZZA, this is more of a longer-term question regarding the payer landscape, as the footprint of the product grows, and given the commentary about reauthorizations and some of the things that you're working through, at least in the first quarter. As we think about INGREZZA beyond in 2020, should we think about a more restrictive payer landscape? Or do you expect that payers are going to put up more roadblocks as volumes of the product grows?

That's number one. And then number two is on opicapone, maybe a little bit early for you to talk about this, but can you give us a sense of where you think gross to net will shake out on that product and also your expectation regarding step edits and prior auths on that?

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

Yes, David, so I'll comment on sort of how we're thinking about the future from a payer perspective for INGREZZA. We've got a little over 2 years in market now. And actually, we've been, as I said earlier, very pleased with the coverage that we've gotten and the high rate of filled prescriptions

versus written prescriptions. We care a great deal about patient access, and we've invested heavily to make sure that patients that need INGREZZA can get access to it. And we're going to continue to do so. You stated rightly that the profile of INGREZZA has grown as the product has grown. But the reality is that we've also been very heartened by the willingness of the providers to go through the necessary steps to get access for their patients to INGREZZA to doing prior authorizations and providing the information that the health plans require in order to evaluate a request for coverage.

The reality is that INGREZZA is the most preferred and the most prescribed VMAT2 inhibitor. And I think that's reflected in the willingness of providers to go to the extra length and to go to the next step in terms of helping their patients to get access to it.

So I don't want to say never. But the reality is that I think that we're in somewhat of a state of homeostasis, where we are now in terms of plans that are looking at making changes to their -- to their coverage criteria. It's always going to be evolving over time, and we'll continue to work with the health plans to help them understand the value that treatment with INGREZZA provides for these patients and also to make sure that their coverage criteria remain appropriate, medically appropriate for this complicated patient populations that develop TD. So we've been successful. We're going to continue to invest in making sure that there's good coverage for these patients because that's our responsibility.

And I think the second part of your question was really around opicapone, maybe what the coverage might look like early on, and I think you asked also about gross to net. I'm not going to comment on the gross to net piece, we certainly don't provide that kind of detail with regards to INGREZZA today. But I will say that just like with INGREZZA, access for patients with Parkinson's disease to opicapone will be critically important, and we recognize that there are treatments out there for patients on -- with Parkinson's on levodopa that are experiencing motor fluctuations.

We've also said previously that we don't expect to price this as a specialty medicine. In other words, it would be a lack price below $600 a month. And that's really part of our strategy to make sure that we have the best possible access for patients. We'll be able to use some of the learnings from our INGREZZA launch and the resources that we've developed in the infrastructure, such as our patient access team, which is in the field to help support our customers understanding what the coverage criteria are. But the reality is, early in the launch, it's not going to be on any formularies. And so we're going to have to help them understand that for these patients, but there will be a formulary exceptions process to get prescriptions approved for opicapone.

So we're going to make sure that we can do everything in our power to make it as convenient as possible for patients and for providers to get those prescriptions written and filled. And we're going to take everything that we've learned from the INGREZZA launch and apply it here to opicapone because we believe that there is as yet a remaining significant unmet need in this patient population. A lot of people that are not optimized with their levodopa therapies that are experiencing hours and hours per day of off time. And we've got a product that we hope to bring to market in the not-too-distant future, that can make a significant difference for those patients.

Operator

And next, we'll go to Marc Goodman with SVB Leerink.

Marc Harold Goodman - *SVB Leerink LLC, Research Division - MD of Neuroscience & Senior Research Analyst*

Hey, Matt, I was wondering if you could talk about the spending and just the push and pulls from year-to-year and how to think about -- any more color you're willing to give us on SG&A versus R&D? Or just on a relative basis, even if you don't want to talk absolutes?

Matthew C. Abernethy - *Neurocrine Biosciences, Inc. - CFO*

Yes, sure, Marc. I appreciate the question. So 2020 is going to be another investment year for Neurocrine, and in particular, on the research and development front. As we mentioned earlier, doubling the pipeline puts us in a place where we're going to have a larger portion of our spend increase year-on-year going towards R&D. And that really sets us up to fund the 3 registrational programs, the Huntington's disease program, CAH as well as the VY-AADC trial as well.

And then in addition to that, funding some of the earlier stage programs, like Xenon and getting the program up and running. So a lot of dollars going behind R&D. On the SG&A front, really focused on continuing to invest dollars behind INGREZZA as well as then the marketing cost associated with preparing for the opicapone launch. So we're looking forward to the investments that we're going to be putting in place next year. We really feel like it's going to position us to continue to evolve our pipeline and really set us up well going into the future.

Marc Harold Goodman - *SVB Leerink LLC, Research Division - MD of Neuroscience & Senior Research Analyst*

Are both line items increasing year-over-year?

Matthew C. Abernethy - *Neurocrine Biosciences, Inc. - CFO*

Yes. Both line items are increasing year-on-year, but we'd say both from a percentage and the dollar perspective, R&D would be going up at a faster rate.

Operator

And our final question will come from Joseph Stringer with Needham & Company.

Joseph Robert Stringer - *Needham & Company, LLC, Research Division - Associate*

This is Joey on for Alan. Another one on opicapone. Maybe you could talk just generally about market share, total market share for COMT therapies given the generic options available?

And maybe just in terms of the patients that you'll be targeting in terms of maybe a breakdown of patients that are currently on therapy who are inadequate responders versus patients who have discontinued the current standard of care therapy and then maybe treatment-naive patients, maybe give a -- if you could comment on where you expect to see the most initial use?

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

Yes. So COMT utilization in the U.S. is about 8% to 10% of the total adjunctive treatment market. And so taking a step back, there's roughly 1 million patients in the U.S. with Parkinson's of those about 70% are currently taking levodopa. And of those, another 70% or so are on an adjunctive treatment. COMT is not broadly used in the U.S. I think because of the deficiencies of the existing treatments historically, the current COMT inhibitors have failed to deliver on the promise of COMT inhibition due to safety issues, tolerability issues and, frankly, in the convenient dosing regimens.

So you do see a relatively higher utilization of drugs from other adjunctive classes, including dopamine agonists and also MAO B inhibitors. Those medications also have their limitations, especially from a tolerability standpoint, we certainly heard loud and clear from our advisers, concerns about, for example, impulsivity, often seen in patients taking dopamine agonists.

So in terms of our approach to the market, obviously, we expect that patients that are currently or have previously been treated with COMT inhibitors would be natural candidates for treatment with opicapone. The other thing to keep in mind is that in this particular category, patients don't usually switch from one adjunctive to another. The physicians tend to sort of stack them up sequentially. And so they may go on one adjunctive, they start to see [winning] results, and then they add a second agent and then potentially a third.

So for us to be successful over time, we expect to displace not only existing COMT inhibitors, but to also expand that COMT class and displace medications from those other classes of dopamine agonists and MAO Bs. Ultimately, we want to be considered the go-to adjunctive treatment when a physician and a patient are having a conversation that their levodopa regimen is no longer adequately controlling, helping to control their

movements that they're experiencing significant off time that's sort of the moment of truth, and they're making a decision about whether to increase the dosing of levodopa or to add an adjunctive treatment.

Given the mechanism of action with opicapone, it makes all the sense in the world of having that conversation around optimizing levodopa before you start to escalate the dosing. Or before you use drugs from other classes that don't optimize the levodopa treatment. So we're really excited about the opportunity here to make a difference from many thousands of patients once we get approval later this year.

Operator

And we have no further questions in queue at this time. So I'd like to return the floor back to Mr. Kevin Gorman.

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

Thank you very much, and I really appreciate everyone's participation in the call today. I do want to make a few closing statements, and I'll start with welcoming our 2 newest board members, Leslie Norwalk and Shalini Sharp. I'm going to use a bit of a sports analogy here in a moment following our -- an exciting Super Bowl game. We have a very good board and have had this board together now for a number of years. We have brought in new members from time to time. And each time that we go out looking to expand the board, generally, we're not looking for a position player. What we're looking for is the best athlete that is out there. And that has worked well for us over the years and welcoming Shalini and Leslie. There, we have 2 very great athletes that we're bringing to this board. And our board certainly deserves a lot of the credit or the success that we've had over the years.

What I would also like to commend here is that our commercial teams and our medical affairs organizations because they also have a direct impact on the absolute stellar results that we've had in the fourth quarter and also for the year of 2019, with INGREZZA, and they are out there on the front lines, advocating for patients each and every day.

Now finally, the ultimate goal for all of us in this industry is to discover, develop and bring life-changing medicines to patients. And at Neurocrine, we are truly fortunate, and we know what to have, INGREZZA, ORILISSA, and potentially soon, opicapone in patients' hands.

Together with our partners, Xenon, Voyager and Idorsia, we are driven to bring precision therapies targeting what have been previously intractable and devastating diseases, and now potentially curative therapies to patients, who need them right now. And that's what we look forward to speaking to you in the future about. Thank you very much.

Operator

Thank you. This will conclude today's program. Thank you, again, for your participation. You may now disconnect, and have a wonderful day.