UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): **November 1, 2018**

AMAG PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-10865	**04-2742593**
(Commission File Number)	(IRS Employer Identification No.)
1100 Winter St. **Waltham, Massachusetts**	**02451**
(Address of principal executive offices)	(Zip Code)

(617) 498-3300
(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Emerging growth company ☐

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

Item 7.01. Regulation FD Disclosure.

The following information and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, except as expressly set forth by specific reference in such filing.

On November 1, 2018, AMAG Pharmaceuticals, Inc. ("AMAG") hosted a quarterly conference call where they discussed AMAG's third quarter 2018 financial results, and also provided an overview of recent business highlights, expectations for 2018 and beyond, and other business matters. A copy of the transcript of the call is furnished herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

AMAG hereby furnishes the following exhibit:

Exhibit Number	Description
99.1	Earnings call transcript, dated November 1, 2018.

This report and Exhibit 99.1 contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein or therein which do not describe historical facts, including, among others, expectations for Feraheme® pricing and market share; beliefs about Feraheme's resiliency to INFeD®; beliefs about the conversion from the Makena® intramuscular to sub-cutaneous ("SC") auto-injector; plans to protect the Makena brand by continued conversion to the SC auto-injector and patient access; expectations about supply of Makena, including when additional supply will be available; beliefs about generic economics; beliefs about Intrarosa® market share; beliefs about Intrarosa media coverage and marketing initiatives; expectations for 2018 financial guidance, including revenues, operating loss and adjusted EBITDA; expectations that the fourth quarter will be a period of continued investment to drive future value; AMAG's key expectations and themes for 2019, including preliminary estimates of EBITDA, product revenue growth, a decline in Makena IM revenues and the belief that Makena SC auto-injector will be sustainable, the planned launch of Vylessi™ (if approved), increased investments in AMAG-423, Vyleesi and Intrarosa and capital allocations from AMAG's balance sheet to fuel its investments; beliefs that AMAG's balance sheet is strengthening; beliefs about stockholder value and AMAG's portfolio; beliefs about annual peak revenue opportunities for AMAG-423, Vyleesi and Intrarosa; beliefs about preeclampsia, the market for, and the anticipated timeline for the FDA's Advisory Committee meeting for, and launch of, AMAG-423 (if approved); beliefs about the Vyleesi Phase 3 studies, including favorable safety profile; beliefs about the market for, and the anticipated timeline for launch of, Vyleesi (if approved); beliefs about the market for Intrarosa; beliefs that the AMAG portfolio is innovative and plans to deliver multiple value drivers; the anticipated regulatory timeline for AMAG's products and product candidates; and plans to undertake additional licensing and acquisition transactions and the expected areas of such expansion are based on management's current expectations and beliefs and are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, the risk that sales of Makena will continue to be negatively impacted by the supply disruption and recent and future generic entries in the market; the risk that AMAG may be unable to gain approval of its product candidates, including Vyleesi and AMAG-423, on a timely basis, or at all; the potential for such approvals, if obtained, to include unanticipated restrictions or warnings and the risk that the costs and time investments for AMAG's development efforts will be higher than anticipated, or that AMAG has over-estimated the market and potential revenues for its products and product candidates, if approved, including AMAG's beliefs about annual peak sales for AMAG-423, Vyleesi and Intrarosa, as well as those risks identified in AMAG's filings with the U.S. Securities and Exchange Commission (the "Commission"), including its Annual Report on Form 10-K for the year ended December 31, 2017 and subsequent filings with the Commission, which are available at the Commission's website at www.sec.gov. Any such risks and uncertainties could materially and adversely affect AMAG's results of operations, its profitability and its cash flows, which would, in turn, have a significant and adverse impact on AMAG's stock price. AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made AMAG disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

SIGNATURES

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

AMAG PHARMACEUTICALS, INC.

By: /s/ Joseph D. Vittiglio

Joseph D. Vittiglio
Executive Vice President, General Counsel, Quality & Corporate Secretary

Dates: November 2, 2018

AMAG PHARMACEUTICALS INC.

Moderator: Linda Lennox
November 1, 2018
8:00 a.m. ET

Operator: This is Conference # 1963718.

Operator: Good morning. My name is (Matthew), and I will be your conference operator today. At this time, I would like to welcome everyone to the AMAG Pharmaceuticals Third Quarter 2018 Earnings Call.

All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key.

It is now my pleasure to turn today's call over to Ms. Linda Lennox, Vice President Investor Relations. You may begin your conference.

Linda Lennox: Thank you, (Matthew). Good morning, and welcome to the AMAG Pharmaceuticals conference call to discuss our third quarter 2018 financial results.

Earlier this morning, we issued a press release. For those of you who don't have a copy, you can access it in the Investors section of our website at

amagpharma.com. Please be reminded that remarks made during this call may include forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We want to emphasize that these forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Please refer to our 2017 Form 10-K subsequent filings with the SEC for a full review of the risks and uncertainties associated with our business.

On today's call, we will discuss certain non-GAAP financial measures with respect to our performance. We use these non-GAAP measures for financial and operational decision-making, and as a means to evaluate our performance because we believe they better represent the ongoing economics of our business. The definitions of our non-GAAP measures are set forth in our earnings release, which was filed with the SEC today.

Copies may be obtained at sec.gov, and in the Investors section of our website. With me on today's call are Bill Heiden, our President and Chief Executive Officer; Nik Grund, our Chief Commercial Officer; and Ted Myles, our Chief Financial Officer.

Let me quickly run through the agenda for this morning's call. Bill will cover third quarter 2018 highlights. Next, Nik will provide commercial update for our marketed products. Ted will then take you through our financial results and updated financial guidance. And lastly, Bill will walk through AMAG's value drivers for the future before opening the call for Q&A.

With that, it's my pleasure to now turn the call over to Bill. Bill?

Bill Heiden: Thank you, Linda, and good morning to all of you joining us on the phone. Ted will take you through our financial results for the quarter in a few minutes, but here are some key highlights for the quarter.

Sales of Feraheme grew 42 percent over the same quarter last year, driven by continuing success of the launch of the broad IDA label. Nik will tell you more in just a minute, including about our strong performance from a competitive perspective. Revenues for the Makena subcutaneous auto-injector grew threefold this quarter versus Q2 and made up 57 percent of the total Makena brand revenues.

We kicked off the Intrarosa direct-to-consumer campaigns, including the unbranded awareness campaign with Emmy-nominated actress, Cheryl Hines. And Nik will tell you in further on the key success metrics to date of that DTC campaign.

As you know, we completed the sales CBR in August. And we used the proceeds from the sale to pay off our high-yield notes, strengthening our balance sheet and delevering the company significantly.

We ended this quarter with nearly $430 million in cash and investments and just $21 million in short-term debt. Our CBR divestiture also underscores our commitment to focus on the development and the commercialization of pharmaceuticals that address unmet medical needs and to continue to build out the portfolio.

And following that theme, just last month, we announced the acquisition of global rights to an orphan drug candidate, now known as AMAG-423, for the treatment of severe preeclampsia, a medical condition that is the leading cause of maternal morbidity and mortality as well as serious adverse outcomes for the newborn, where there are no approved treatments.

It's been a busy and productive quarter, and so let's jump right in, and now let me turn the call over to Nik for an update on our commercial products. Nik?

Nik Grund: Thanks, Bill. I am pleased to be able to share with you the strong commercial execution across our portfolio in the third quarter, starting with Feraheme. Our Feraheme team had another great quarter with revenue of $37 million compared to just $26 million last year, which as you heard is a 42 percent increase in a highly competitive marketplace. We grew volume by over 30 percent, primarily by taking share, nearly 3.5 percentage points gained year-over-year.

In addition to the strong clinical profile of the product and our sales forces' ability to differentiate the product with physicians, performance-based contracting has been key to Feraheme's growth. Through the implementation of a disciplined pricing strategy, we have been able to drive consistently rising net revenue per gram, which grew 11 percent versus the third quarter of last year.

On our last earnings call, we talked about conducting a pilot program to test how we can help women suffering from iron deficiency anemia due to gynecological issues, including abnormal uterine bleeding, and who are under the care of OB/GYNs.

The divestiture of CBR in August freed up some capacity in our maternal health sales team, so we formally launched the pilot in September. This is aimed at educating OB/GYNs of the limitations of oral iron and referral opportunities to treat women with IV iron, who are suffering from iron deficiency anemia due to gynecological issues, with our goal to continue to

grow the market for IV iron and see that more patients benefit from Feraheme therapy.

Our sales team did a phenomenal job in continuing to convert accounts to Feraheme during the third quarter. As we discussed on our second quarter call, INFeD was experiencing a product (stockout) and that INFeD volume was distributed among all of the different IV irons, including Feraheme. As expected, INFeD did return to the market early in the third quarter, but I am pleased to show you that Feraheme was the only IV iron that maintained market share versus prior quarter and gained volume.

As you can see in the first row in the table on the right on Slide 7, every other IV iron lost share and volume back to INFeD. Importantly, in our largest volume segment, Hematology and Oncology shown in the bottom half of the table, we saw Injectafer lose significant share and volume, while Feraheme volume grew. So excellent progress in growing both volume and revenue with the expanded label, and we expect this growth going forward as we continue to take share from the competition.

Now let's turn to Makena. On the left of Slide 9, you can see that third quarter 2018 sales of Makena were just over $80 million. And you can see how that breaks down between intramuscular, subcutaneous auto-injector and authorized generic. 57 percent of branded revenue in the third quarter was from subcu auto-injector versus 13 percent since second quarter, demonstrating the significant progress we continue to make converting the market from IM to subcu.

Revenue from the authorized generic represents about 15 percent of the total Makena revenue in the third quarter of 2018. All along, we said that we expected a generic to Makena to be approved midyear, and that's exactly what happened. So when a generic came to market in July, w

e were well prepared for it, as was our authorized generic partner, Prasco, who launched immediately following the July availability of generic Makena.

We authorized Prasco to launch both the single and multi-dose intramuscular formulations, determining that having both SKUs available to Prasco would allow them to create a competitive advantage and potentially win a higher share of contracted business. Prasco initially captured about 75 percent of the generic market share. But as we stated, we do anticipate multiple generic players in the market by year-end and expect Prasco's share to come down.

Lastly, our primary contract manufacturer of the intramuscular formulation has been experiencing production delays, which has resulted in challenges supplying the market with the intramuscular formulation. As the market for Makena IM began to transition to generics, we made the decision to direct our limited supply in third quarter to the authorized generic, which meant we have got an out-of-stock situation with the branded single-dose IM product.

The shortage has resulted in significant reduction in channel inventory, which impacted our quarterly results. It has also likely hastened the transition from branded Makena intramuscular to generic IM. Though as we have stated our authorized generic partner took the large majority of share in the third quarter, they did so at a net price that is significantly lower than branded product.

We have been working with our IM contract manufacturer as well as our second source IM supplier to accelerate the availability of additional supply, and believe the issue could be resolved in the early part of 2019. To date, only the intramuscular formulation is affected by these production delays. Subcu auto-injector and the authorized generic remain available.

Our first priority continues to be to protect the brand, which means promoting the benefits of the subcu auto-injector over IM and thereby converting the market to subcu. And as you have seen, we have shown good progress. We continue to see strong physician support of branded Makena. Currently, 56 percent of prescriptions that come through Makena Care Connection state dispensed as written, which means that a prescription cannot be automatically switch to a generic. This compares with 40 percent last quarter.

Makena Care Connection continues to be a valuable offering to physicians to ensure access to branded Makena. With generics in the market, we have been and will continue to work with our managed care partners to ensure that the value proposition of the subcu auto-injector is reinforced, which may include some future price concessions.

Our second priority shown on the right is to participate in the economics of the generic market through our partnership with Prasco.

So in summary, we're working hard to defend the Makena brand and continue to feel good about our ability to maintain a portion of this market with our next-generation auto-injector, and that Prasco will continue to be a strong player in the generic IM market segment.

Now let's turn to Intrarosa, our first-in-class therapy to treat moderate-to-severe dyspareunia, a common symptom of vulvovaginal atrophy, or VVA, in postmenopausal women. As shown on the left of Slide 12, we continue to accelerate the growth of total prescription volume. As shown on the right, since launch, we have grown the number of total prescription to nearly 150,000, and the health care provider base to more than 11,000 prescribers. These are nice increases over the second quarter numbers.

Commercial insurance coverage for Intrarosa is strong and is currently 83 percent of all commercial labs. Importantly, overall market share continues to grow and is currently 4.5 percent. Our market share in those patients covered by commercial insurance is 6.3 percent. As a reminder, we've had no access to Medicare patients, whereas the older estrogen products were covered by Medicare.

In June, we began our condition awareness campaign, which included digital advertising and a significant presence on Facebook. In September, we launched our PR campaign with the help of Emmy-nominated actress, Cheryl Hines. Coverage from our unbranded campaign was significant, including Cheryl Hines on the morning talk show The View, where she not only promoted the return of Curb Your Enthusiasm, but encouraged women to start open dialogue about painful sex due to menopause.

Between both earned and paid media, we have been able to generate more than 360 million impressions, which was significantly better than benchmark for similar campaigns. This condition awareness campaign drove 650,000 unique visits to our unbranded internet site, pausesexpain.com.

The branded campaign is off to a good start. We also launched this campaign in September, which includes an integrated media plan and patient support program as well as an option for visitors to immediately discuss treatment with a telemedicine physician.

In fact, we've already seen a number of women click through to our telemedicine partner, where we assume a portion have already received an Intrarosa prescription.

The branded campaign has reached over 10 million women significantly ahead of our benchmark, which has resulted in a 30 percent increase in v

isitors to intrarosa.com, and we'll continue our efforts through the end of the year and into 2019. These early signs are encouraging and convincing that women are seeking information, which we believe will result in a new prescription. While some women will go through telemedicine, many will ask about Intrarosa at their next annual appointment with their OB/GYN, so we expect to see a more significant impact as we move through 2019.

Now I'll turn it over to Ted for an update on the quarter's financial results. Ted?

Ted Myles: Thanks, Nik. As a quick reminder, all the financial information that we're presenting this morning excludes the historical financial results of CBR. That divestiture was accounted for as discontinued operations in those operating results, and the impact of transaction itself appears in a separate section of our financial statements.

Slide 15 illustrates our GAAP and non-GAAP results for the three months ended September 30, 2018, compared to the same period a year ago. Product revenue for the third quarter of 2018 decreased 2 percent to $122 million. As Nik mentioned, the entrant of a generic competitor and supply issues have had an adverse impact on our intramuscular Makena product revenues. We are, however, quite pleased with the performance of our authorized generic partner. Their successful launch has enabled us to participate in the generic IM market.

Additionally, the Makena subcu auto-injector has exceeded our expectations with $40 million in revenue for the quarter, and continues to grow from this strong position in the market, as physicians, nurses and patients experience the many benefits of this differentiated product. As we look to the future of the Makena franchise, early indicators suggest that the Makena subcu auto-i

njector will provide a sustainable source of revenue for us for many years to come.

A great example of durable revenue growth is Feraheme, which grew 42 percent over the third quarter last year. We are very pleased with yet another strong quarter as that team continues to execute.

Intrarosa contributed $4.9 million in the quarter, up over 50 percent versus Q2. While we're pleased with the volume growth and the continued increase in new scripts, net price is lagging behind our expectations. We continue to expect that this will improve over the coming quarters as we implement some adjustments to our co-pay program.

Looking at the operating results for the third quarter of 2019, as compared to the same period in 2017, there are a couple of important takeaways. First, the $254 million in GAAP operating loss in 2017 was driven by a $319 million Makena IM-related noncash impairment charge as well as an expense reversal of $50 million related to a reduction in contingent consideration. The operating loss of $19 million in the third quarter of 2018 was impacted by the $12.5 million of IPR&D, or in-process research and development, that we booked in connection with our acquisition of AMAG-423 in September.

On a non-GAAP basis, you can see that adjusted EBITDA, as represented by the black bars, was $30 million in the third quarter of 2018 as compared to $45 million in the third quarter of 2017. This decline is in line with our expectations and is consistent with our stated plans to evolve AMAG's business strategy. Specifically, the increase in SG&A expenses in the third quarter of 2018 was driven by increased investments to support the continued commercialization of the broad Feraheme label, Makena subcu auto-injector and Intrarosa.

As we enter 2018 and published our full year financial guidance in January, there were a number of unknowns, including the approval of the Feraheme broad label and Makena subcu auto-injector as well as the timing, the number and the behavior of potential Makena IM generics. It would have been hard to imagine that we would be in such a great position today, and we're proud of all the achievements year-to-date that allow us to, once again, increase our financial guidance in what has proven to be a pivotal year for our company.

This morning, we increased our revenue guidance reflecting a midpoint of $480 million, which is an increase of $70 million since the beginning of the year. And we're also able to increase our adjusted EBITDA midpoint to $120 million for the year, an increase of $50 million from where we began in 2018.

As we look to 2019, we are planning for a year that will be characterized by continuing growth in the Makena subcu auto-injector, Feraheme and Intrarosa, while investing aggressively in the products that will build an even more exciting future.

Slide 17 shows the year-to-date financial results and our updated guidance for the full year. Our expectations for fourth quarter revenues and adjusted EBITDA are fairly obvious, approximately $100 million and breakeven respectively. This quarterly number is a good starting point as investors start to think about full year 2019.

Our budgeting process is still underway, so I can't provide specifics at this time, but we do want investors to have the benefit of our early perspective. Key themes for 2019 will include continued growth from Intrarosa, Feraheme and Makena subcu auto-injector offset by the decline in Makena intramuscular products. We plan to use positive cash flows to fund the anticipated launch of Vyleesi, assuming FDA approval in the first quarter of 2019; the continuation o

f the Intrarosa direct-to-consumer campaign; and the acceleration of the AMAG-423 clinical trial program.

We're making these investments now in order to develop durable revenue products in the future to create long-term value. Adding all of this up, our preliminary view is that spend is going to exceed our expectation of revenues in 2019. We expect negative EBITDA in 2019 in order of magnitude of about $50 million. Again, our budgeting process is still underway, so this is, obviously, preliminary, and we'll provide financial guidance in January, consistent with our past practice.

AMAG is in a fortunate position to be able to make these investments, not only because we have products producing significant cash flow, but also because we have a strong balance sheet with nearly $430 million of cash on hand.

With our strategic evolution mind, since mid-2017, we have eliminated approximately $800 million in debt, including $475 million of high-yield notes that we retired in September. We've also extended our maturities, so that we now have only $21 million of near-term debt. Overall, we have aligned our balance sheet specifically to support our evolving business strategy, and we're now poised to execute on this plan. We have several very compelling investment opportunities and the financial means to pursue them.

I'll now turn it back to Bill to talk about the AMAG value drivers and what the investments we are making today could deliver to patients and shareholders tomorrow. Bill?

Bill Heiden: Thanks, Ted. On the left-hand side of this slide are the historical AMAG value drivers, starting with Makena, which has been a big contributor to revenues over the last four years; Feraheme; Intrarosa, which is still in launch

phase; Vyleesi right around the corner with a March PDUFA date; and our newest addition AMAG-423.

But when I look to the future, as the company continues to transform, I see the real value drivers as being almost in opposite order to the historical view. As I look ahead, I believe that AMAG-423 has significant potential in an area of high unmet medical need; Vyleesi is a product that addresses a medical condition affecting 1 in 10 women; Intrarosa competes in a market of approximately 20 million women, where 90 percent are currently not being treated; Feraheme, as you just heard, is up over 40 percent from a year ago and is off on a whole new leg of growth; and finally, Makena. We've already successfully converted a significant portion of the market to our next-generation subcu auto-injector and believe it's differentiated and can deliver durable revenues over the long term.

Of course, in order to realize the exciting potential of these products, we need to invest aggressively today. So why am I so enthusiastic about these new products?

Let's look at AMAG-423. Preeclampsia is a real unmet medical need, with serious potential health consequences from mother and baby that puts a huge economic burden on the health care system, and there are no approved treatments. It's a disorder that occurs during the pregnancy and affects about 140,000 women a year in the U.S. alone, severe preeclampsia affecting 50,000 women. As you can see on the right, we believe this product represents a peak revenue opportunity of more than $1 billion per year in the United States, and internationally the prevalence preeclampsia is even higher.

What about Vyleesi? Vyleesi is an on-demand treatment for premenopausal women, who suffer from low desire or low libido with associated distress. T

his is a condition that occurs in approximately 1 in 10 women. This drug was a subject to two large Phase 3 clinical trials, where we hit the co-primary endpoints agreed on with the FDA with high statistical significance.

Vyleesi is a product that is not taken every day. It is used only in anticipation of sexual activity, three to four times a month on average in our clinical trials and has a favorable safety profile, including no interaction with alcohol.

Vyleesi is currently under review with the FDA, and we're now preparing for the Ad Com in January, and we have a PDUFA date of March 23. The market opportunity is large and only a portion of the women with this condition would need to be treated to see Vyleesi annual sales grow to $700 million in the U.S.

And Intrarosa, indicated for the treatment of moderate-to-severe dyspareunia or painful intercourse associated with menopause, shown on the right, a condition affecting 20 million women in the U.S. with less than 10 percent being treated. And the number one reason for not seeking treatment, women report that they don't want estrogen. And estrogen has been the only local prescription option for the last 50 years up until last year.

Intrarosa is the only local non-estrogen treatment for dyspareunia. It has a differentiated mechanism, which stimulates the intracellular production of androgens and estrogens, improving the health of the vaginal tissue and symptoms for these women. All the other products in the category have boxed warnings that warn patients who take those other therapies, that they may be at increased risk of cancer, cardiovascular disease and dementia, and Intrarosa has none of those warnings.

We launched this last year and now have a broad group of physicians, who are writing. We just, in the last few weeks, launched our direct-to-consumer campaign that should bring a portion of the several million women, who are untreated, forward for Intrarosa therapy, and we believe that it could represent more than a $500 million a year peak revenue opportunity.

In closing, displayed on Slide 23 is AMAG's full portfolio of pharmaceutical products, a diversified set of products in women's health care and hematology, at various stages of development and commercialization. We are well positioned to continue to invest in the development and commercial success of these products as well as presume additional potential business development opportunity. This slide lays out a number of key near- and medium-term milestones that we believe will drive significant additional shareholder value.

And with that, we'll conclude our prepared remarks and open the call for questions. (Matthew)?

Operator: Certainly. At this time, if you would like to ask a question, please press star one on your telephone keypad.

Your first question comes from the line of Jessica Fye with JPMorgan. Your line is open.

Jessica Fye: Hey, guys. Thanks for taking my question. I want to make sure I heard you correctly on some of the 2019 comments. Is that negative $15 million, 1-5, or negative $50 million, 5-0, on non-GAAP EBITDA? And I'm curious how you think about Makena for '19, kind of what should we think about as flowing into that number from a Makena standpoint?

Ted Myles: Jess, this is Ted. Good morning. Thanks for the question. So let me start in reverse order. I want to caveat, we haven't finished our budget process. We

don't want to guide -- get ahead of ourselves in terms of '19, but we look at the subcu auto-injector of $40 million a quarter last quarter and that $40 million to $50 million per quarter rate, we think this is a good place to think about for that product over the long term. Again, $40 million to $50 million per quarter for the subcu auto-injector.

And then in terms of the EBITDA loss for 2019, it was 5-0, $50 million is our -- again, very early view. We're in the budget process. We'll update the Street when we complete that and issue guidance in January.

Bill Heiden: Nik, any other comments on Makena to look to 2019?

Nik Grund: Yes. Only that we've actually seen a very good physician receptivity towards the subcu. It continues to grow. We saw really, really exciting growth between quarter two to quarter three in subcu. And our dispense as written campaign through Makena Care Connection really demonstrates that physicians really value that service offering in a way to get and ensure that patients have access to branded subcu Makena.

Jessica Fye: OK, great. And can you help us think about how much of that spend in '19 might be from bremelanotide launch investment, i.e. to the extent that product hits like a regulatory hiccup? What kind of flexibility you might have?

Ted Myles: As we've said before, Jess, big picture, we have a very variable cost structure, and the numbers we've put forth assume a successful Vyleesi approval and launch. So in January, we'll give a little bit more granularity, but I don't want to unpack how much relates to Vyleesi.

Jessica Fye: OK, sure, understood. And then I apologize if I missed it, but what was third quarter gross to net on Intrarosa? And is it possible to elaborate at all on the changes you were alluding to for the co-pay program that could help address

those? And also just kind of a housekeeping question. What was the magnitude of the inventory hit you referenced that hit Makena in the quarter? Can you quantify that?

Bill Heiden: Sorry, Jess. So let's take it. Now, gross to net -- Ted, do you want to …

Ted Myles: So gross to net increase from Q2 for Intrarosa was about $70, it increased to about $80 in Q3.

Bill Heiden: Yes. And then, Jess, this is Bill. In terms of the co-pay program, one of the changes or one of the issues we've referred to is these -- the high deductible plans. And so one simple modification that we'll likely make going forward is just to put a limitation on benefit. And so that patients who have $10,000 deductible plans, ultimately they're going to move a cash pay model, and we will not be able to for those patients to guarantee a minimum at $25 co-pay forever. So that's one modification that we'll make.

And then, Nik?

Nik Grund: Yes. And so, Jess, your last question on kind of inventory and the magnitude of the inventory drawdown on -- around Makena. We've kind of talked in the past that we keep roughly between three and four weeks of inventory on hand at any time, given the supply constraints. We do that down roughly a week and a half, so 50 percent reduction in inventory levels over that time period. So if you look at the quarterly revenue, you can probably get a sense for what that really translates to.

Jessica Fye: OK, super. Thanks for taking the questions.

Bill Heiden: Thanks, Jess.

Operator: Your next question comes from the line of Ami Fadia with Leerink. Your line is open.

Ami Fadia: Thank you. Good morning. I had two questions. Firstly, how do we think about the enrollment rate for the preeclampsia program? Give us a sense of some of the initiatives you are undertaking. And how should we think about the timeline of enrollment? And then the second question is with regards to the cost structure. As we head towards the turn of the year and expect some generic competition for Makena, how do you think about the cost structure as you continue to sort of put more resources behind Intrarosa and bremelanotide into next year?

Bill Heiden: Great, thanks, Ami, this is Bill. Let's start with your first question on enrollment for the AMAG-423 program. We are right in the midst now of transferring responsibility from the previous sponsor. There's a bit of administrative work that goes on. We actually have to change the sponsor and replace the protocol around those few IRBs, so there's a bit of switchover that takes place. And so enrollment actually, we pushed the pause button, while you make that transition. And then I think by early '19, we'll really hit it hard.

As we mentioned, we will be expanding the number of sites. We're currently working with a CRO to establish the exact number of sites. We've said previously up to 50 sites in the U.S. and internationally. We may even go higher because our goal is to accelerate, dramatically accelerate enrollment in this trial. And we expect to have the trial fully enrolled by the end of next year.

In terms of cost structure, I'll let Ted make some comments.

Ted Myles: Sure. Thanks, Bill. And thanks for your question. So as I mentioned, we have a very variable cost structure. We're just now making our way through

the budgeting process. And so we have yet to make all the decisions in terms of how we allocate capital across the brands.

I will say that we see Makena subcu auto-injector and Feraheme, for that matter, as significant cash flow -- positive cash flow within our business in all cases, so we can titrate investment as those products grow and then make investments in the other areas. Again, we'll provide more detail and actual guidance for '19 in January, as we typically do.

Nik Grund: The only thing I might add to that is as you saw in quarter three with an excess capacity in our maternal health sales force, we're able to slide a nice Feraheme pilot in there. So when we look (at our) Vyleesi launch, we will be utilizing some of our existing commercial capacity to be able to support that product moving forward, a nice synergy opportunity as we built out our women's health platform.

Ami Fadia: Thank you.

Bill Heiden: Thanks, Ami.

Operator: Your next question comes from the line of David Buck with B. Riley FBR. Your line is open.

David Buck: Yes. Thanks for taking the question. Just maybe one for Bill. Can you -- you talked a little bit about the longer-term outlook for both Vyleesi and also Intrarosa. Can you talk about just medium-term or short-term 2019, 2020? What kind of ramp you need to see to basically justify sort of the current investment, particularly in Intrarosa, given where the run rate is now?

And just for Ted, for the fourth quarter, can you just clarify the expectations for Makena? Are we essentially just looking at the auto-injector and

essentially the authorized generic in the fourth quarter because you're essentially close to out of stock on the IM prefilled syringe? Thanks.

Bill Heiden: Sure. Thanks, David. So in terms of our expectations around Intrarosa, as Nik mentioned, the direct-to-consumer campaign just started literally in the last few weeks. The early metrics are beating all benchmarks, so we're really pleased with the early metrics.

As Nik mentioned, we also have a telemedicine option. That's one where we can actually see patients clicking through from our Intrarosa site to go through to telemedicine. We don't know what happened exactly beyond that, but we assume many of those patients are getting an Intrarosa prescription directly through a telemedicine provider. And so we're going to watch these metrics very carefully, even over the next few weeks through the end of the year, which will inform our guidance for 2019 on Intrarosa.

Vyleesi, again, that will be embedded in our 2019 guidance. I have to say from a revenue perspective, I wouldn't -- I'd be pleasantly surprised if this were a huge revenue driver in 2019. There will be some investments. We'll try and synergize and utilize our -- some of our existing commercial capacity. But I think there will also be some incremental investment anticipated in 2019, and those were, I think, embedded in Ted's comments.

David Buck: Maybe just to follow-up …

Bill Heiden: And in terms of …

David Buck: I'm sorry, if I could cut you off for a second, maybe this is more for Nik. But -- so what is the plan in terms of Vyleesi, separate sales force expansion versus using some of the Intrarosa reps?

Nik Grund: Frankly, it's a little bit too early to tell, right? So as we go through the final budget planning and go-to-market strategy, a lot of it is around where do women present. As you know, this condition is -- struggles with low awareness at the physician level on diagnosis pathways.

So some women with the condition are ending up at OB/GYNs, where we're very, very, strong in both maternal health and Intrarosa sales forces, but also some end up in sexual health experts as well as psychiatrists or psychologists. So making sure that we know exactly where patients are presenting is an important part of how we go to market. But I do anticipate a significant amount of synergies between our sales forces as we bring that product to market.

Ted Myles: Hey, David, in terms of Q4, so the implied math there on the slide is about $100 million in revenue and about breakeven on adjusted EBITDA, as I spoke to. I think your question was around Makena within that $100 million. And as I pointed out, the subcu auto-injector of about $40 million in Q3, we think we can grow from there. Also some expectations around the authorized generic in terms of the branded product, we'll see what supply -- how the supply disruptions work out.

Bill Heiden: And I think we've been fairly conservative on our expectations for fourth quarter Makena branded IM as well as -- and as we start to think about 2019 if these supply issues get resolved, then there could be some upside there.

Operator: Your next question comes from the line of Bill Maughan with Cowen and Company. Your line is open.

Bill Maughan: Good morning and thanks. So if you could just update us on the current expectations for novel Makena IM generics, both in terms of quantity and timing of potential new entrants? And is there any reason to believe that they

will or will not be more aggressive on pricing than the current market? And then kind of along the same lines, how have your interactions with payers evolved as the Makena landscape has sort of developed in over the recent months?

Nik Grund: Bill, this is Nik. So we continue to anticipate multiple generics. We've had pretty reliable competitive intelligence throughout 2018, and we continue to see a lot of active DMFs out there. Now we don't know exactly who is paired up with who from an API standpoint, but we continue to anticipate a couple more generics here by the year-end.

Your second question around payers. Our payers are actually have -- the reaction and our contact with payers has been very, very encouraging. They recognize the value that certainly auto-injector brings to this patient population. So we haven't seen a tremendous amount of adverse activity. There have been payers who are looking for price concessions. We've tried to limit those to the IM.

But the interactions, they see the value in the product, they're willing to engage, they're giving us a heads up if they are thinking about taking action, which is really all you can ask for. Coming back after they take action to try and change that is much harder than if you get in front of it and have active dialogue moving forward. So overall, I think, the payers recognize the value and are, at least, willing to work with us.

Bill Maughan: All right. Thank you very much.

Nik Grund: Thanks, Bill.

Operator: Your next question comes from the line of Serge Belanger with Needham & Company. Your line is open.

(Tim): This is actually Tim calling for Serge. I just have a question for Vyleesi. What kind of product label are you guys expecting for this product once it's launched?

Bill Heiden: Sure, Tim. This is Bill. Certainly, we are hopeful to get a pretty clean label. As we've mentioned, this product has very strong efficacy data with primary endpoints that were agreed upon with the agencies, on the efficacy side. We expect -- or hope that we'll get a strong label there.

And then in terms of safety, I think you are aware in the category, there have been some safety concerns, specifically around the prior product that was approved, which is a once-a-day therapy, ours is an on-demand therapy. So it's only used in anticipation of sexual activity, three to four times a month. And I think that helps in terms of how one would view the safety and efficacy profile. The prior drug did have an issue with interaction with alcohol. We have done safety interaction studies, and there is no interaction with alcohol. So we're hopeful that we're going to get a pretty clean label here, but of course that will be the subject of negotiations with the FDA as we head into the March PDUFA date.

(Tim): Thank you.

Operator: Again, if you'd like to ask a question, please press star one on your telephone keypad.

Your next question comes from the line of Bill Tanner with Cantor. Your line is open.

Bill Tanner: Yes. Thanks for taking the question. I had a question, Nik, just on maybe some general color on the physician uptake of the auto-injector. What it looks like, just in terms of physicians using it on few patients or is it in entire practices? And then you mentioned, obviously, with the payers recognizing the value, just kind of curious the value proposition for them would be for that -- would be what just in terms of -- obviously, is this going to come down -- this can't really be coming down to a cost gain, I guess? So just any color what it -- now that you're pretty far into the launch, what it looks like, the types of docs that are actually using the product?

Nik Grund: Yes. Bill, thanks, always happy to talk about auto-injector as it has gone pretty well. The color on it with regard to physician usage is really -- I hate to say it this way, but physicians aren't (stocking both). Once they decide that their practice -- and there are a lot of logistical benefits to auto-injector within their practice, and we've gone through -- don't have to have or use a syringe, needle sticks, changing needle heads and, obviously, intramuscular pain, all those things that go along with the benefits of a subcu from a logistics standpoint don't have to have patients disrobe all those other pieces.

So what we really see is physician offices, if they're going to go, they're kind of all in unless there's some kind of hiccup in reimbursement. And as we've kind of quoted earlier, we've done a really nice job of creating almost equal reimbursement and access for patients to the subcu auto-injector. So we're seeing, we'll call it, complete physician practice flips, whereas physicians that haven't opted it yet, they also don't stock in their shelves, so they're usually primarily IM in that case. But we're pretty happy with the progress we've made so far, and we see continued growth moving forward.

Bill Heiden: And the only thing I'd say, Nik, is just to remind in your comments, in your prepared remarks, you were mentioning the value of the Makena Care

Connection. I think that continues to be a huge value here because physicians, nurses like the Makena auto-injector to script those to the Makena Care Connection. And if there are any reimbursement discussions that we -- those get handled in Makena Care Connection, and so that Makena Care Connection continues to be a real value add as we sell them, the auto-injector to our customers.

Nik Grund: And, Bill, your last part was the payer value proposition. So a lot of it comes down to is the physician acceptance. So as our volume is growing, if we get physicians use it, payers are seeing that acceptance in the marketplace. They also understand that physicians are using dispense as written. And we've had good relationships over the year. So there is a number of ways for which we have high-value rebates with payers today that gives some protection. So we've had good constructive dialogue.

I imagine, frankly, that subcu will be under some price pressure as more generics come for market, but we do -- and our market reaffirms this, we do believe that it can substantiate a price premium moving forward for subcu.

Bill Heiden: And we've already seen the significant discounting in the generic market. And in spite of that, the subcu auto-injector is maintaining a significant share. So I think that's why our comments on -- and I believe that this is going to be a nice durable revenue stream going forward.

Bill Tanner: And just one follow-up to that, I appreciate that color. I mean, no pun intended, but is this the auto-injector or do you think it's kind of sticky in terms of the practices when they adopt it, they stick with it versus, I mean, just, I guess, I'm wondering how on a salable is that market share from a pricing perspective for the IM, as an example?

Bill Heiden: I like the way you put it, Bill. We're going to use that. This is sticky going forward.

Bill Tanner: No attribution needed for me. Thanks.

Nik Grund: All right. Thanks for the question, Bill.

Operator: Your last question comes from the line of Chris Raymond with Piper Jaffray. Your line is open.

Chris Raymond: Hey, guys. Thanks for taking the question. Just another question here on the subcu -- the Makena subcu auto-injector. So I remember when you guys acquired Makena, a big theme was the conversion of major state Medicaid administrations and payment for the branded drug over compounded 17P. So just now, I guess, with the generic alternative available and still, I think, a pretty large Medicaid component to the payer mix, should we be looking for major Medicaid sort of larger states like Texas and California, et cetera? Is that something we should be watching for in terms of their payment decisions? I know you've talked about a nice run rate for the auto-injector, but how much at risk is that if you see some states making decisions to reimburse only for the generic?

Nik Grund: Chris, it's a great question. As you know, and we've talked about it in the past, Medicaid is something important to price-sensitive customers. So our pricing in Medicaid states is actually on the lower side of our average pricing and that creates an interesting and nice buffer against them wanting to -- in order to adopt to generic. That gives us time to get utilization in state Medicaid offices to see the benefits, patients, hopefully, to see the benefits and create some resiliency or resistance there to switching in generics.

As of today, all of the big state Medicaid plans, we haven't had any disadvantage situations in state Medicaid. So it's proving to be an area where we believe there's a strong hold for us, given the logistics, benefits of the subcu as well as the pricing that's existing in that state Medicaid population.

Chris Raymond: OK. And then just -- I know, you guys don't want to get too much into 2019 since you're not issuing formal guidance, but just on this EBITDA, I guess, projection. I think I heard you guys saying the auto-injector run rate is about $40 million a quarter, which I think would be like $160 million or so for 2019. I guess, if the IM contribution is minimal, should we be looking at that for Makena going forward as a revenue run rate?

Bill Heiden: Well, so a couple of things, Chris, and I appreciate the question. The subcu auto-injector, it's early days. As you said, for 2019, we're on a nice run rate. We think once this market sort of stabilizes and because of the aggressive discounting on the generic side, we may be close to stable, we think we can actually continue to grow the auto-injector going forward. And we'll try and give a little more color when we get specific about 2019.

The other piece that I mentioned is as we look towards the end of 2018 and even into 2019, our expectations around the intramuscular form are fairly conservative, given some of the supply issues that we faced with third-party supplier. We're working very hard to resolve those. And if we can resolve those, I think then there's some upside to the forecast around Makena.

Chris Raymond: Great. Thank you.

Bill Heiden: OK. Thanks, Chris.

Operator: And we have no further questions at this time. I will now turn the call back over to Mr. Bill Heiden for any closing remarks.

Bill Heiden: Thank you very much, (Matthew). So as you've seen, we've made important progress in the first nine months of 2018. We still have plenty of work ahead. We look forward to continuing to update you on our progress through the remainder of this year, and to giving you an overview of our 2019 expectations in January. We want to thank you all, again, for joining us here this morning, and this concludes today's call.

Operator: And this concludes today's conference call. You may now disconnect.

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