

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

SCHEDULE TO

Tender Offer Statement under Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934

GENTIUM S.P.A.

(Name of Subject Company (Issuer))

**JAZZ PHARMACEUTICALS ITALY S.R.L.
JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**

(Names of Filing Persons (Offerors))

Ordinary Shares, no par value per share
and
American Depositary Shares each representing one Ordinary Share
(Title of Class of Securities)

The CUSIP number for the Ordinary Shares, which are not traded on U.S. markets, is 37250B922.
The CUSIP number for the related American Depositary Shares is 37250B14.
(CUSIP Number of Class of Securities)

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CALCULATION OF FILING FEE

Transaction Valuation	Amount of Filing Fee*
N/A*	N/A*

* Pursuant to General Instruction D to Schedule TO, a filing fee is not required in connection with this filing because it relates solely to preliminary communications made before the commencement of a tender offer.

Check the box if any part of the fee is offset as provided by Rule 0-11(a)(2) and identify the filing with which the offsetting fee was previously paid. Identify the previous filing by registration statement number, or the form or schedule and the date of its filing.

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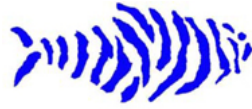
- Third-party tender offer subject to Rule 14d-1.
- Issuer tender offer subject to Rule 13e-4.
- Going-private transaction subject to Rule 13e-3.
- Amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer.

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>
99.1	Transcript from investor/analyst conference call held on December 19, 2013.
99.2	Email from Jazz Pharmaceuticals' Chief Executive Officer to employees, sent on December 19, 2013.
99.3	Letter from Jazz Pharmaceuticals' Chief Executive Officer to Gentium employees, sent on December 19, 2013.
99.4	Media Standby Statement, first used on December 19, 2013.
99.5	Gentium Transaction Internal Communications Q&A, first used on December 19, 2013.
99.6	Jazz Pharmaceuticals Overview Presentation, first used on December 20, 2013.

Jazz Pharmaceuticals 12.19.13 Phone Conference



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[Start of recorded material]

Operator:

Welcome to the Jazz Pharmaceuticals conference call. Following an introduction from the company, we will open the call to questions. I will now turn the call over to Kathee Littrell, Vice President of Investor Relations at Jazz Pharmaceuticals.

Katherine Littrell:

Thanks, Jason. Welcome, everyone, and thank you for joining our conference call this afternoon to hear about the strategic transaction that we have just announced with Gentium. Joining us for today's call are Bruce Cozadd, Chairman and CEO; Jeff Tobias, head of R&D and Chief Medical Officer; and Kate Falberg, CFO. Following some prepared comments, we'll open the call for your questions. I'll also note that posted on our website and available in conjunction with the webcast are slides for your background information.

Let me remind you that some of the statements we will make on this call relate to future events, instead of historical facts, and are forward-looking statements. These include statements related to the anticipated consummation of the tender offer for Gentium shares, and the timing and benefits of the transaction; expected financing for the transaction; anticipated product portfolio; commercial, development and regulatory plans with respect to Defitelio and the timing of these plans; expectations and projections; future financial results, and future growth opportunities and potential.

These forward-looking statements involve numerous risks and uncertainties that could cause actual events, performance and results to differ materially. These risks and uncertainties are identified and described in our press release, the slide presentation accompanying this call, and under "Risk Factors" in our Form 10-Q for the quarter ended September 30th, 2013. We undertake no duty or obligation to update any forward-looking statements we make today.

I'll now turn the call over to Bruce.

Bruce Cozadd:

Thank you, Kathee. Good afternoon, everyone, and thanks for taking time to join us on this call. We're pleased to announce that we've entered into a definitive agreement with Gentium, and expect to make a cash tender offer for all of the outstanding Gentium ordinary shares and American depository shares of \$57 per share, in a transaction that is valued at approximately \$1 billion. We're continuing to deliver on our growth strategy.

We believe that the transaction announced today clearly aligns with our mission, and is a great strategic fit. It would add a recently approved orphan product, Defitelio, to our portfolio in the European Union. Defitelio was approved in October for treatment of severe hepatic veno-occlusive disease, or VOD, and we believe there is potential to develop the product for approval in other indications, such as prevention of VOD and acute GvHD, or Graft versus Host disease.

Defitelio clearly addresses an unmet medical need, as it is the only approved drug for severe VOD, a life-threatening disease.

Defitelio would leverage our specialty pharmaceutical expertise and is highly synergistic with Erwinase, as both products will be marketed to hematologists and oncologists in the EU by a relatively small sales force.

Defitelio has very good exclusivity with orphan status in the EU for ten years, and a complex supply chain and proprietary manufacturing process that begins with animal-derived materials.

We believe this transaction is value-creating for our shareholders, with an attractive return on investment, and is expected to be accretive to non-GAAP adjusted earnings per share in 2014 and beyond.

Gentium is an Italian biopharmaceutical company, with approximately 75 employees, that was founded in 1993. The company is run by a strong and experienced management team, and we are pleased that many of them have agreed to share their expertise during the transition. Gentium has its headquarters and with commercial operations based in Zug, Switzerland.

Let me now turn the call over to Jeff to discuss Defitelio.

Jeffrey Tobias:

Thank you, Bruce. Venous-occlusive disease, or VOD, is a life-threatening complication of hematopoietic stem cell transplants. The disease was thought to begin with injuries to the hepatic or liver venous endothelium. This injury can occur as a result of exposure to chemotherapy or radiation. It is often part of the conditioning regimen that is given prior to initiating stem cell transplants.

Following the injury, the vasculature can become occluded, and this can lead to liver injury, and then, in severe cases, liver injury and multiple organ failure. And this condition, called severe VOD, is associated with high rates of morbidity and mortality that can exceed 80 percent.

Studies have reported a wide range of incidence rates, however, on average, VOD occurs in approximately 14 percent of patients undergoing hematopoietic stem cell transplants, or HSCTs. Defitelio is the first and only drug approved in the EU for the treatment of severe VOD in adults and in children following HSCT.

Currently, the product is used on a named-patient basis in many countries, and is recommended in both EU level and national level guidelines. At this time, in the U.S. there are no approved treatments for VOD.

I'd like to take a few moments to review some of the findings from the phase 3 study of Defitelio in the treatment of severe VOD. The

study was performed with a historically controlled, multi-center, open label, phase 3 study to determine the safety and efficacy of defibrotide, or Defitelio, at 25 milligrams per kilogram per day. And this was to treat patients who developed severe VOD following stem cell transplants. The clinical trial had efficacy endpoints of complete response and survival, measured at day 100. Complete response, or the percent of patients who had complete resolution of sVOD by day 100 and complete resolution of any multi-organ failure was 24 percent for the defibrotide arm and 9 percent in the control arm. At day 100, the survival rate was 38 percent in the defibrotide arm, compared to 25 percent in the historical control arm, which is a 52 percent increase in survival.

These results demonstrate a significant and clinically important improvement in both complete response and survival at days 100 as compared to the historical controls. The most common side effects with Defitelio are hemorrhage, hypotension, and coagulopathy. Gentium currently has an ongoing treatment IND study in the U.S., and we've included some data from an interim analysis of that study, in the accompanying slide deck on our website. But I'll review a few of those data here.

These were recently presented in the 2013 ASH — American Society of Hematology — meeting in New Orleans. The data reported on 284 patients who were treated with Defitelio. Complete response at day 100 in that cohort were 29 percent, and the survival

rate was 48 percent, results that were similar to those observed in the phase 3 treatment study, which I described above.

Gentium filed an NDA in the U.S., in August of 2011, and subsequently voluntarily withdrew the NDA following some correspondence from the FDA identifying several potential "Refuse to File" issues regarding, among other things, the completeness and accuracy of their datasets.

Gentium has been working towards the resubmission of an NDA for defibrotide and had publicly disclosed its expectation that it would submit the NDA in the first half of 2014. We've planned to continue to assess what we believe would be the most appropriate path for potential approval of defibrotide in the U.S. We plan to update investors on our plans for this NDA once we determine our regulatory path, after the closing. We are very pleased to have the opportunity to add Defitelio to our portfolio. In addition to its role in the treatment of severe VOD, we are also excited to evaluate Defitelio in other potential indications, such as the prevention of VOD. Now, I'll turn the call back over to Bruce.

Bruce Cozadd:

Thank you, Jeff. Defibrotide is currently available on a named-patient basis in over 40 countries, through a number of distribution partnerships. The European Medicines Agency has granted Orphan Drug Designation for defibrotide for the treatment of VOD, for the prevention of VOD, and for the prevention of Graft versus Host disease.

In the U.S., defibrotide is available to patients via an expanded access treatment IND. Orphan drug status and Fast Track Designation have been granted by the FDA to treat VOD. Gentium has a license and supply agreement with Sigma Tau to commercialize defibrotide for the treatment and prevention of VOD in the Americas. Under that agreement, Gentium is responsible for development.

As we look toward the commercial opportunities, the EU is the largest potential market, with more than half of the worldwide HSCT procedures in 2013.

Of the approximately 35,000 patients who undergo the procedure in the EU annually, approximately 6,300 are considered at high risk for the development of VOD. Based on data presented recently at ASH, we would plan to conduct a study in this patient population to evaluate whether there is a benefit from prophylactic therapy. The incidence of VOD in the EU is approximately 3,600 patients, and we know from the literature and physician research that approximately one-third to two-thirds of the patients are considered eligible for treatment.

For the European commercial launch of Defitelio, we are planning to incorporate the product into our hematology-oncology business that includes Erwinase. We would anticipate that the commercial launch material will be available in the first quarter of 2014, and the

launch meeting is tentatively planned in the first quarter to coincide with the European Society for Blood and Bone Marrow Transplantation meeting in Milan. During 2014 and 2015, our emphasis would be on establishing the foundation for a common EU price for Defitelio.

The pricing and reimbursement negotiations will be ongoing, and we anticipate early resolution or so-called "free pricing" in countries such as the UK, Germany, and the Netherlands.

In summary, we're both excited about the near-term commercial opportunity to treat patients with severe VOD in the EU and eager to continue the development of this compound in other indications where there are significant unmet medical needs. Let me now turn the call over to Kate.

Kate Falberg:

Thanks, Bruce. At our offer price of \$57, which is a premium of 26 percent to the 60-day volume-weighted average price, the total purchase price for the transaction is approximately a billion dollars. We expect to fund the transaction through a combination of cash on hand, the proceeds from an incremental term loan, and revolver borrowings under our existing senior-secured credit facility. We have secured a \$500 million financing commitment from Barclay's, which is subject to standard conditions. We expect the interest rate on the incremental debt to be approximately 3 to 3.5 percent.

Post this transaction, with approximately \$600 million in additional debt outstanding, our pro forma leverage ratio based on adjusted EBITDA is expected to be less than 2.5, and we expect that it would decline rapidly as earnings grow and as revolver debt is repaid. I also want to note that we temporarily suspended our share repurchase program during this quarter to preserve cash in anticipation of this transaction and potential future business development opportunities.

We plan to initiate the tender offer shortly and expect to close the tender offer in the first quarter of 2014. We're pleased that shareholders representing 15 percent of the outstanding shares of Gentium have already agreed to tender their shares.

In the slide deck, we have provided a summary of the expected incremental 2014 revenues, non-GAAP operating expenses, and adjusted EBITDA, assuming that the transaction closes on January 31 with 100 percent of shares tendered.

As Bruce mentioned, we expect to begin the process of obtaining pricing approvals in various European countries in the first quarter, and that process is likely to continue into 2015. We would expect added revenues in a range of \$50 to \$60 million, reflecting continued named-patient revenues and commercial sales commencing during the year, with a gross margin that is consistent with our current business. Defitelio will be marketed to many of the same centers as Erwinase, and therefore, we expect that there would

be a small increase in the number of representatives and medical science liaisons in our EU business.

The expected adjusted EBITDA contribution in 2014 is a range of \$20 to \$30 million, and of course, we expect that would increase significantly in future years as revenues increase. We expect that the transaction would be modestly accretive to our adjusted EPS in 2014 and more substantially accretive in years beyond. In closing, we believe that Defitelio would be an important growth driver for our top and bottom line for many years. We also would maintain a strong financial position, with flexibility to pursue additional attractive investment opportunities, as we continue to deliver on our mission to serve patients and generate long-term shareholder value.

Katherine Littrell:

Thank you, operator, and we'd now like to open the call for questions.

Operator:

Ladies and gentlemen, if you have a question, please press star followed by one on your phone. If your question has been answered or you'd like to withdraw the question, please press star two. The first line comes from the line of Jason Gerberry with Leerink Swann. Please proceed.

Jason Gerberry:

Hey, good evening, and thanks for taking the question. Just a couple. Can you just talk about your confidence, your thoughts, on preserving the exclusivity of the asset beyond 2023? And your thoughts on the regulatory barriers? And then just a second — can

you confirm — I guess this looks like, you know, the accretion from the deal is mainly from acquired EBITDA. Can you just confirm that there's no operational or tax synergies? Thanks.

Bruce Cozadd:

Yeah, I'll take the first part of the question, which goes to exclusivity. I think we'll have more to say on that over time. I think the summary comments we made, that not only do we have the regulatory exclusivity through the orphan designation, but we believe from what the product is, how it's produced, and some of the IP around that, there are also some reasons to believe this product will have long exclusivity. And let me hand the financial part of the question over to Kate.

Kate Falberg:

In terms of synergies, as we noted Gentium today has about 75 employees. And we have assumed that we will need at least 75 employees to effectively launch the product in Europe. So this is not a cost-cutting merger per se. And on the tax side, we believe that the tax rate applicable to the incremental profits from Defitelio would be in the high single to low double digits for a number of years. We think it slots very well into our international tax structure, so we certainly think that this does leverage the fact that we do have an efficient corporate structure.

Jason Gerberry:

Great. Thanks.

Operator:

Your next question comes from the line of Louise Chen with Guggenheim. Please proceed.

Louise Chen:

Hi. Congratulations on the deal. I had a few questions; thanks for taking them. The first question I had was Bruce, you've always said that the value of your low tax basis survives beyond 2014 given all kinds of tax inversion deals that we've seen. Any updates or expansion on your thoughts on this matter? And then the other question I had was how did you come across this Gentium opportunity? I know you were looking at a bunch of different things. How did you weigh your different options? Thanks.

Bruce Cozadd:

On the tax side, we have a tax structure that we believe is good for our current business, but also allows us to competitively acquire additional assets into our business. We don't see that changing. We don't believe other currently or recently announced transactions really change that. Could there be changes in tax laws in the future? Absolutely there could be. I think some of those could actually be beneficial, particularly to the extent the U.S. decides at some point that one of the reasons companies pursue some of these transactions is because on a relative basis the U.S. tax rate of course is very, very high.

How did we come across this opportunity? I'm sure when all the documents get filed, you'll see a little bit of background of transactions. But I'll just say generally we've made a real commitment and investment in our corporate development capabilities in the company. We've got great leadership of that function. We've got a great team in that function. We've added

resources across some of our operating groups to specifically support that function. And we've broadened the range of target opportunities that we're evaluating. Obviously this transaction brings with it a European commercial business as well as some development opportunity. That's not something that really would have been on our radar screen before mid-2012 when we completed the EUSA transaction.

So we are looking at European businesses. We are looking at U.S. businesses. We're looking at global businesses. We're looking at development programs. We're looking at all those things we've been talking about that would be built on our existing platform and provide the kind of growth we can achieve from our existing franchises, from smart investments in corporate development, and some select investments in R&D. So not every transaction will look the same, but this was one that we thought fit particularly well.

Louise Chen:

Thank you.

Operator:

Your next question comes from the line of David Amsellem with Piper Jaffray.

David Amsellem:

Thanks. Just a couple. Wondering if you can elaborate on the issues involved in the Refuse to File in the U.S., and maybe just give a further color on how you would size up the U.S. market opportunity, the U.S. dollar opportunity for the product. Thanks.

Bruce Cozadd: Yeah. Let me ask Jeff to comment, although we'll probably keep our comments to a minimum on the original decision to withdraw the NDA. And then I can make a comment about the U.S.

Jeffrey Tobias: Right. Well, to a large extent it was related to the way and types of data that were being proposed to be presented, as well as some of the issues in just how it was put together. A large number of the comments relate to what kind of data the FDA was looking for that was not going to be in that original package. So Gentium took those comments and withdrew their NDA to go back and try and address those issues.

Again, I think one aspect that was raised has to do with the use of historical controls. That is something that's particularly tricky, especially in these types of diseases where it's often difficult to have a concurrent placebo control. And so there were questions that were raised regarding these and the nature of the historical controls. These were issues that were also raised within the CHMP review, but were then subsequently satisfied to the needs of the CHMP where the drug got approved in Europe.

Bruce Cozadd: And then on your question about the U.S. commercial opportunity, as a reminder the U.S. commercial rights are held by Sigma Tau, not by us. And they're probably in a better position to comment — if they choose to — on their view of the U.S. commercial opportunity. For us, this transaction was primarily about acquiring the European commercial business, and then with

the potential to expand the drug's indication over time on the basis of the number of HSCT procedures. U.S. market, a little bit smaller than that.

And of course our economics in the U.S. market would only be partial, because of the Sigma Tau rights. So from a "value to Jazz" perspective, a little less important. And as we model that, returns to our shareholders from this transaction, we modeled out a number of scenarios for timing of potential U.S. entry and what it could be, and we're comfortable that this price fairly reflects a range of possibilities there. But I don't think we can probably comment much beyond that.

David Amsellem:

Bruce, if I may, would you contemplate down the road trying to acquire full U.S. rights? Is that something you would explore?

Bruce Cozadd:

I would say our deal to buy Gentium was to buy the company as it exists, realizing that in this case we're getting European commercial rights. They happen to fit beautifully with our European business. To us in this deal, we would participate in somebody else's commercialization of the product, and that's how we're looking at it.

David Amsellem:

Thank you.

Operator:

Your next question comes from the line of Gene Mack with Brean Capital.

Gene Mack:

Hi. Thanks for taking the questions. I've got just a few. The first one is, "What took you so long?" No, really what I was wondering, Bruce, in the \$57 price per share, what were you contemplating there? Was that just on the numbers of patients for VOD? Did you have any assumption there for prophylaxis? Did you have any assumption there for GvHD? That's first.

And then second, just a point of clarification. I don't recall Gentium actually ever got an RTF in the June filing before that came. That's just a sticking point. But I'm just wondering if that's the case. And then I also wanted to clarify — I thought Sigma Tau's rights to defibrotide ran for about eight years following a U.S. approval if one is granted, and then would revert back to Gentium. Can you just confirm that that's still in place, or is there maybe some sort of change of control provision that will keep the economics the way they are out in perpetuity. And then, just on the tax rate numbers, commercial operations based on Switzerland, do you plan on moving that around anywhere? Will the commercial operations for Defitelio stay in Switzerland, and that's how we should contemplate how the tax rate's domiciled? I guess that's it for now. I'll bother you guys later.

Bruce Cozadd:

So, Gene, it's clear you're familiar with the company, as we knew. You know, in terms of the price we're paying, at this point, the product has one approved indication in the EU. You're aware and we're aware of some of the data that exists that would suggest the

opportunity for successful development beyond that. That is something we intend to pursue for sure in prevention of VOD.

I would say we're not in a position to say right now where we'll go beyond that, although we know there are opportunities — you mentioned GvHD is one. Obviously, those have potential value, but that value comes down the road and after successful development. It's not a sure thing, but we think it has promise, and certainly is something we'll pursue.

Jeff, you want to comment on the particular regulatory question?

Jeffrey Tobias:

Yeah. You're right. I misspoke. They didn't have a refusal to file, they had issues that would lead to refusal to file had they submitted it.

Bruce Cozadd:

And then on commercial operations, I would say let the Jazz and Gentium teams get together post-transaction to figure out how we, together, can make the most of our combined business at that point, which, of course, is not just the Gentium product but the Jazz product too. You know, I think the combined teams are going to be a great team to take this forward, of course, together. We'll still need to add some people beyond that to fully take care of this opportunity. But a little too early to comment on that. And then, Kate, on the Sigma-Tau structure?

Kate Falberg: So, Gene, no change to that agreement between Gentium and Sigma-Tau, so that remains in place.

Gene Mack: Great. Thanks so much, guys. Congratulations on this well-constructed deal. Thanks.

Operator: Your next question comes from the line of Gary Nachman with Goldman Sachs.

Gary Nachman: Hi, good afternoon. A couple. First, could you give us a sense of ranges of pricing per patient that we should think about in Europe? It seems like you're working on that, but any color would be helpful. And also, just generally, on the dynamics in Europe with respect to pricing. And then, anything else, Bruce, that Gentium has in the pipeline, aside from expanding the indication for the key product, that we should think about in terms of the valuation? And then, lastly, are there rights to other regions outside of the Americas separate from the EU that you could potentially take advantage of? Or should we really think of this as just an EU opportunity? Is there potential to expand in other parts of the globe as well?

Bruce Cozadd: Thanks, Gary, for the questions. On pricing per patient, not all that much we can say yet since that's a work in progress. Clearly, this is a life-threatening condition in a small number of patients where this treatment really does make a difference. As such, it commands quite a benefit the way most payers and governments will look at

that. Until we've got some pricing approvals, we're probably not going to have a lot to say from a specific standpoint.

I think in broad strokes, the pricing is probably in the same range as the European pricing for Erwinase, just to give you a sense. This is tens of thousands of dollars per patient, with a lot of variability. Dosing is based on weight, so different from pediatric to adult. Some difference in number of days of treatment. So it's not as though there's one fixed price per course of therapy. But hopefully that gives you some sense.

On the pipeline, we really think of the pipeline as being largely this product and where we could take it more broadly in the future. I think in the slide that Kate included in the deck, you can see there are some other revenues from API supply that's clearly revenue and has some value, but I don't think of it so much as pipeline.

And then other regions, yes. Outside of the Americas, where Sigma-Tau has the rights, there are opportunities to go beyond just the EU.

Gary Nachman:

Okay, thanks.

Operator:

Your next question comes from Jonathan Eckard with Citi.

Jonathan Eckard:

Thank you for taking questions. I apologize because I joined the call late. So if these were addressed during the prepared comments, forgive me. But it seems like this deal certainly is building up the

EU commercial infrastructure. Based on the business today, where do you see the most advancements or expansion of the current products and how you could probably maybe expand some of the commercial efforts for some of the other products in Europe?

And then also, during the prepared comments I did hear that you were suspending the stock repurchase for this and potential future acquisitions or business transactions. So I was wondering, after this deal is closed, where will the company stand financially with regards to the amount of capital that you could have on hand to do additional transactions going forward? Thanks.

Bruce Cozadd:

Good question, Jonathan. On the EU, yeah, this will expand our capability and footprint in the EU a little bit. And that could have benefits to other products. Although very clearly, our primary focus is going to be on Erwinase, one of our core growth franchises, and Defitelio. So that is where we're going to put the majority of our focus in terms of growth, particularly growth with assets that we believe have the opportunity to grow in the current markets, have additional development opportunities beyond that, and have good exclusivity. So the products are very aligned in that way. And let me hand the second question about deal capacity over to Kate.

Kate Falberg:

Yes. So during the prepared remarks, I mentioned that our pro forma leverage post the transaction would be under 2.5. And obviously, you know we generate significant cash flows. We would expect that leverage ratio to come down pretty rapidly after closing.

We think that we've got continued great access to capital, and we are continuing to look at other BD opportunities, and are quite comfortable that additional transactions will be affordable for us.

Jonathan Eckard: Very helpful. Thank you.

Operator: Your next question comes from Greg Fraser with Bank of America.

Greg Fraser: Thanks. This is Greg Fraser for Greg Gilbert. You mentioned the complex supply chain. Maybe you could just comment on your confidence in having stable and sufficient supply for the EU market?

Bruce Cozadd: Yeah. I don't have a sophisticated answer to that one, other than we're confident we've got stable supply for the European market.

Greg Fraser: Okay. That's an answer. I'm not sure if I missed this earlier, but did you comment on the timeline for the prevention indication, and how big that opportunity could be?

Bruce Cozadd: I'm sorry, could you repeat that?

Greg Fraser: Did you comment on the timeline for the prevention indication, and how big that —

Bruce Cozadd: Yeah, we haven't commented on that yet. I suspect that's something we talk about post-closing in terms of specific plans for a

development program, some specifics about that, and what we expect it would lead to in terms of timing for a potential indication.

Greg Fraser:

Okay, what about the size of the opportunity?

Bruce Cozadd:

So the size of the opportunity is very significant. Obviously, in terms of number of potential patients, if you go up the funnel to try to prevent VOD, you're obviously not looking at the patients with VOD, but who are at risk, and we have a slide in our deck — I think it's slide 15, maybe — that walks through some of the numbers of patients and gives you a sense for the potential addressable market, but we're not claiming you'd ever get every one of those patients. But there certainly is a potential for a larger opportunity.

Greg Fraser:

Great, that's helpful, thank you.

Operator:

And your next question comes from the line of Josh Reigelhaupt with Stifel.

Josh Reigelhaupt:

Hi, guys. This is Josh in for Annabelle. Just kind of following along that line for the label expansion, can you tell us what the difference in the treatment paradigm is between a prophylactic setting and an acute setting and whether that involves more dosings or more frequent dose or what not?

Jeffrey Tobias:

So the dose for treating severe VOD as it comes on is the 25 mgs per kg per day for 21 days or until there's resolution of the severe

VOD. That's obviously you're intervening at the time the disease is present. If you're trying to prevent it from occurring, you start early on. You'd start in a wider population, but probably one that's aimed at a higher risk of developing VOD. There was an initial study that was performed that began treatment during the conditioning phase and continued it out for 30 days, and they found that there was a difference in the incidence of VOD, using that type of regimen. So overall, you can see that they're not too far different in their overall exposure, but the population, certainly, would differ significantly.

Josh Reigelhaupt:

Okay, thank you.

Katherine Littrell:

Okay, operator, I'm going to just make a couple — well, one closing remark. We just want to thank all of you for joining us on the conference call. We have one more person — it looks like they joined — so we will go ahead and take that last call, and then we'll close after that. Thanks.

Operator:

Okay. Thank you so much. The next question is from Katie Brennan with BMO Capital Markets.

David Maris:

Hi, it's David Maris. A couple things. First, on the product acquisition, you mentioned that there are a number of different partnerships for distribution. Are you contemplating bringing those in house and building out a bigger footprint, yourself? And then secondly, Bruce, I see what you're doing. I don't know if others see

it. You know, first Ireland, then Italy. You're clearly planning retirement at some point, picking all the nice places.

But when you look at the deals that you're currently looking at, should investors be thinking that your real goal is more of the similar-type deals, product-oriented deals, or are you looking at things that are — seem to be a little bit more common in specialty pharma recently, of acquire and cut or assimilate?

Bruce Cozadd:

Yeah, good questions, and happy birthday, David.

David Maris:

Thank you very much.

Bruce Cozadd:

On the distributors, we think Gentium's put some good distributors in place. And just like EUSA has a combination of direct markets, where they have our own set of people on the ground, we also use distributors there, so complimentary in that way and consistent. Other parts of the question? My retirement strategy, no comment on that. Oh, types of deals. Yeah, it's interesting. We just so happen to have done a series of deals in Azur and EUSA and now Gentium where cost cutting has really not been part of the equation.

But I don't think that means we're against transactions like that, because we're not. It's just that in each one of these cases the combination of us and the company we were coming together with really needed to grow to take full advantage of the asset we were acquiring. If and when we acquire an asset where that's not

necessary, could there be the opportunity for more efficient commercialization or development? Absolutely.

But not in this case. In part, you're looking at an organization in Gentium that's accomplished a lot with not a lot of employees and would have had to scale up, themselves, to go to the next stage, and so think about the synergy here not as cost cutting, but we have a bunch of the people they would've had to hire.

David Maris:

Great. Well, thank you very much.

Operator:

We have one more question from the line of Douglas Tsao with Barclay's.

Douglas Tsao:

Hi. Good evening. And congrats on the deal. I joined late, so my apologies if it's been asked before, but obviously, we saw previously a lot of focus on CNS in the business and certainly on the business development side, and now, post-EUSA, we've seen deals in oncology and now this, which seems to be somewhat related, you know, how are you seeing things in terms of your therapeutic areas of focus and thinking broadly and, you know, I know you're always staying true to the orphan drugs or orphan-focused, you know, are you going to continue, you know, obviously there are a lot of orphan conditions in oncology — is this how you're looking at the world right now, as if this oncology platform really is going to be a key driver on a go-forward basis?

Bruce Cozadd:

Yeah, Doug, you know, we've emphasized with each of the areas we've gone into the importance of a real specialty physician audience, the ability to go out and make an impact with a good drug, with a relatively focused, well-trained, capable sales force, a good medical team, and we felt that the places we've been thus far, including narcolepsy, with Xyrem, and pediatric oncology with Erwinase, and interventional anesthesiology with Prialt, have met those criteria.

This one's a great fit with where we already are. Hem-onc is perfect on top of Erwinase, so a perfect fit. Does that mean we will only now grow in the areas we have? No. If we find others that match our criteria for the types of products we're looking for, really differentiated, meet a medical need that's significant, good exclusivity, but also meet our commercial structure, sort of those small, focused sales forces, we're perfectly willing to go into new areas, as well.

Douglas Tsao:

And I guess it's a different way of asking the question, but does this lower the threshold, given the portfolio, for you doing deals in hem-onc?

Bruce Cozadd:

No, I think we're really careful any time we look at a deal. If it would be a great fit with an area we're already in, we'd love that, but we need to think about what our true capabilities are and can we handle, you know, what does it mean to bring one more product

into the portfolio? And we just need to make sure we can handle that in a way that benefits our shareholders.

It's easier to look at deals like that. Our expertise tends to be higher. I think we're smarter. We can do better diligence. We can move faster. So we often do gravitate to deals like that. But again, we'll look at things that fit perfectly with what we do already, but we will look at other areas for expansion, as well.

Douglas Tsao:

Okay, great, thank you very much. And happy holidays.

Bruce Cozadd:

Happy holidays.

Katherine Littrell:

Okay, operator, we want to thank you again and thank all of you who joined our call, and this will end the call for now.

Operator:

And ladies and gentlemen, that concludes the conference. Thank you so much for your participation, and you may now disconnect. Have a great day.

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Dear Jazzicians:

Today we have made an announcement that we expect to significantly grow our European business: We have entered into an agreement to acquire Gentium S.p.A., an Italian biopharmaceutical company whose strengths and focus complement our own. We will be discussing the transaction during upcoming conference calls that will be confirmed soon, but, in the meantime, I wanted to share some background on this planned acquisition – financially the largest we will have made to date – and what it would mean to our patients, our operations and our employees.

First, I want to repeat something you have heard many times: A key element of our strategy is to grow by acquisition, diversifying our portfolio with marketed or close-to-approval products that make a real difference to patients with specialized, unmet needs. I bring this up again today because when you look at Gentium, you will see that it is a remarkable fit with this strategy.

Gentium's lead product is defibrotide, a treatment for a life-threatening orphan condition called severe hepatic veno-occlusive disease. This is a complication affecting adults and children undergoing stem cell transplants to treat cancer. These severely ill patients have no approved therapies to prevent or treat a condition that otherwise has an 80 percent fatality rate. Patients will have a novel and potentially life-saving option with the EU launch of defibrotide (as Defitelio), which is planned by end of the first quarter. Thus, bringing Gentium into our organization is, at its core, a tangible and terrific example of our growth strategy in action.

The similarities between Jazz Pharmaceuticals and Gentium are readily apparent, even beyond our mutual focus on helping patients. We both celebrate innovation and collaboration as key drivers of our successes.

Jazz Pharmaceuticals and Gentium are also highly complementary on a number of levels. Welcoming Gentium into our European business would greatly bolster our international presence, cementing our position as a leading multinational specialty pharma company. Our success with Erwinase demonstrates the strong relationships Jazz Pharmaceuticals has built with key physicians in the hematology/oncology space, and we expect that our clinical and commercial expertise in reaching small, targeted patient and physician populations would speed the growth of defibrotide.

I'm sure you are wondering what today's announcement means to all of us as employees, especially those in Europe. We are truly excited to welcome Gentium's employees to Jazz Pharmaceuticals. Over the next month or so, there are many details to work out as we plan for the closing of the transaction and moving forward to combine our businesses, which we expect to happen in the first quarter. But overall, we are confident that today's announcement can create tremendous new opportunities for many employees.

This is a defining moment for our company. We are very selective about potential acquisitions, and we feel very confident that bringing Gentium into Jazz Pharmaceuticals is right for patients, our companies and our employees. I hope you'll join me for one of our conference calls to discuss this news. I also hope that, in the meantime, you will share in my enthusiasm for this exciting step forward.

All the best,

Bruce

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Dear Gentium Employees:

You have no doubt heard the news about the agreement between Jazz Pharmaceuticals and Gentium S.p.A. I wanted to reach out and introduce you to our company.

Jazz Pharmaceuticals was founded in 2003 and, like Gentium, we are focused on helping patients with highly specialized and significant unmet medical needs. Our passion for patients brings us to work each day, and our culture celebrates innovation and collaboration, attributes that will be enormously valuable as we begin working together in 2014.

Over the past several years we have made growing by acquisition one of our key priorities. We have achieved a good deal of success in executing this strategy, welcoming two European-based companies (Azur Pharma and EUSA Pharma) into our company within the past two years and recording impressive financial growth. We have learned a great deal from these transactions and have since grown our European business into a strong enterprise, developing deep clinical and commercial expertise, relationships, and a leadership team that we are confident can help fuel the growth of Defitelio™ (defibrotide). We are very selective about the acquisitions we opt to pursue, and we have specifically chosen Gentium because of our companies' similarities and complementary strengths.

Today's news is very exciting and significant for all of us at Jazz Pharmaceuticals, and we look forward to the expected closing of the transaction in the first quarter. This transaction would be our largest acquisition in terms of investment to date, and we expect Gentium would significantly grow our European business in particular.

But just as important is what this announcement means to you.

I know you have many questions about the structure of our company, how Gentium would fit in and what this would mean for your career. It will take time for us to determine the details regarding organizational structure, but generally, we expect that Gentium would become part of our European business with no immediate changes to your facilities or locations. We truly look forward to getting to know more about you all. We expect that today's announcement can create significant opportunities for those in our European business – including Gentium – and we think you will find our culture, development opportunities and record of success very attractive.

Today is the start of a journey we hope to take together to join our companies in 2014. All along the way, we intend to do everything we can to keep employees updated about our integration progress and opportunities available to employees as we begin working together. I know you have many questions, and we commit to answering them as soon as we can.

I co-founded Jazz Pharmaceuticals more than 10 years ago and am dedicated to helping patients and ensuring Jazz Pharmaceuticals is a great place to work. We have achieved so much in the past decade, yet we will accomplish so much more in partnership with Gentium. I can't think of a more exciting way to start the New Year.

On behalf of our company's entire leadership team, we look forward to welcoming you to Jazz Pharmaceuticals.

All the best,

Bruce

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Media Standby Statement***To be used only in response to media requests for Jazz comments regarding Gentium pre Tender Offer launch***

Jazz Pharmaceuticals and Gentium S.p.A. announced that they have entered into an agreement for Jazz Pharmaceuticals to acquire Gentium, a biopharmaceutical company based in Italy. The planned combination of Jazz Pharmaceuticals and Gentium is highly synergistic, as both companies are dedicated to bringing differentiated therapies to patients who have high unmet medical needs.

The transaction would add Defitelio™ (defibrotide) to Jazz Pharmaceuticals' diverse development and commercial portfolio. Defitelio is the first therapy approved in the European Union for the treatment of severe hepatic veno-occlusive disease (sVOD) in adults and children undergoing hematopoietic stem cell transplantation. Severe VOD is a severe and life-threatening orphan disease with no approved treatments. Jazz Pharmaceuticals' commercial and clinical expertise in orphan diseases in the area of hematology / oncology, and its existing multinational infrastructure, will help realize the value of Defitelio to patients who have limited options.

The deal also represents Jazz Pharmaceuticals' continued execution on its growth strategy. Jazz Pharmaceuticals expects the acquisition of Gentium to be important to its multinational development and commercial operations, short- and long-term revenue opportunities, and to offer high-growth potential. Jazz Pharmaceuticals expects to close the acquisition during the first quarter of 2014, subject to the satisfaction of customary closing conditions.

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Gentium Transaction
Internal Communications Q&AEmployee Q&A**1. What are the key similarities between Jazz Pharmaceuticals and Gentium?**

Both organizations are dedicated to helping patients with significant unmet medical needs and to doing so through innovation and collaboration, attributes that have fueled our respective successes and will continue to do so in the future.

2. How does this transaction align with our strategy?

We have been very clear about our strategy to acquire marketed or close-to-approval products that align with our mission to bring forth meaningful therapies that make a real difference to patients in specialized areas. As such, Gentium is a solid fit with our strategy. We believe that the addition of Defitelio™ (defibrotide) would further diversify our portfolio, and add a new orphan product that has potential for short and long-term revenue generation, high growth, and expansion of our multinational commercial platform.

3. How does this transaction compare to others we've completed?

This transaction is, in terms of investment, the largest we've signed to date, and it would be particularly significant for growing our international business. The acquisition of EUSA Pharma provided us a commercial platform in Europe; the addition of Gentium builds on this. Also, Defitelio would further diversify our product portfolio. Strategically, it's a solid fit with our business development strategy.

4. Why did Gentium agree to be acquired?

Gentium was interested in combining with a company that could help bring Defitelio™ (defibrotide) to market in the EU, and our commercial infrastructure, relationships and clinical expertise would enable just that. Moreover, we are confident that our experience in reimbursement, educational programs and patient outreach can be a tremendous asset in growing Defitelio.

5. How will Gentium be integrated into our existing structure?

It will take time for us to determine the details regarding organizational structure, but in large part and generally speaking, Gentium would become part of our European business.

6. How many employees does Gentium have, and where are they?

Gentium has approximately 75 employees. They are headquartered in Villa Guardia (Como), Italy, own a manufacturing plant in Villa Guardia (Como), Italy and have a commercial operations center in Zug, Switzerland.

7. Will there be changes to management of either company?

We do not expect any changes to Jazz Pharmaceutical's board or executive management team.

8. What will happen to existing locations of Jazz Pharmaceuticals and Gentium?

It will take some time for us to determine all the details of the combined company, but at this time we are not planning any changes to facilities or locations.

9. Will there be any layoffs or organizational changes as a result of this transaction?

While we can never rule out staffing or organizational changes in the normal course of doing business, we are pursuing this transaction to grow.

10. What will commercialization of Defitelio (defibrotide) mean to our field sales organization?

We would be able to leverage the existing EUSA commercial platform and sales force which promotes Erwinase. Gentium has some sales leaders and a few sales representatives at this time as part of their organization. In addition to these individuals we would expect there to be a small increase in the size of the sales force to focus on the launch of defibrotide in the EU, thereby creating potential new opportunities for current employees.

11. What are our plans for Gentium's manufacturing operations?

We would intend to retain Gentium's manufacturing presence, which includes a plant in Villa Guardia (Como), Italy.

12. What will change for employees?

We would be truly excited to welcome Gentium's employees to Jazz Pharmaceuticals. Over the next few weeks (as we work to complete the tender offer), there will be many details to work out as we determine how best to combine our operations, and we will keep employees updated as integration moves forward.

13. When do Jazz Pharmaceuticals and Gentium officially become one?

We expect the transaction to close during the first quarter of 2014. Until then we will be separate companies.

14. What can we expect in terms of communication?

We are committed to communicating regularly with employees and sharing information as soon as we can. We aim to strengthen our internal communication with each transaction we complete; to that end, we formed our Communications Council earlier this fall to help keep all employees updated on important company events such as this transaction. Should you have questions, please contact your manager or someone on the Communications Council.

15. How/when do I make contact with my counterparts at the other company?

Since we are still separate companies until close, please do not proactively reach out to your new colleagues until asked to do so.

16. What should I do if a reporter or investor approaches me?

Please refer all investor questions to Kathee Littrell: Ireland, + 353 1 634 7887, or U.S., + 1-650-496-2717 or media questions to Laurie Hurley, Ireland, + 353 1 634 7894, U.S., +1-650-496-2796.

17. What should we tell external stakeholders and business partners who ask about this transaction?

You can refer to the publicly available information in the press release and investor presentation which is located on the investor section of www.jazzpharmaceuticals.com.

18. What is a Tender Offer?

A tender offer is a way of acquiring a publicly traded company by purchasing a certain number of the shares of the company directly from the shareholders. The tender offer is at a fixed price, usually at a premium over the current market price of the target shares, and is usually contingent on shareholders selling a certain number of their shares during a limited period of time. Typically, at the end of a tender offer transaction, the offering company (here Jazz) owns a controlling number of shares in the target company (here Gentium).

19. Whom do I contact with questions?

Please direct questions to your manager or any member of our Communications Council.

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Jazz Pharmaceuticals Overview



Our Mission

Jazz Pharmaceuticals is a dynamic specialty biopharmaceutical company that identifies, develops and commercializes innovative products to address unmet medical needs in focused therapeutic areas, always keeping in mind our mission to improve patients' lives.



Living Our Core Values is Key to Our Success



Integrity

Passion

Collaboration

Innovation

Pursuit of
Excellence

What's in Our Name?



Inspired by the talented jazz musicians who come together, each a specialist with individual style, to make music in concert.



A philosophy that each talented team member, working in collaborative and creative teams, contributes to a common goal to improve patients' lives.



Patient-First Approach

We bring valuable therapies to help patients overcome challenging, complex diseases.



We provide comprehensive support services to help ensure access to and safe and appropriate use of these therapies.

Executing on Growth Strategy

June 2005
Acquired
Orphan Medical



January 2012
Merger with
Azur Pharma



February 2013
Agreement with Concert
Pharmaceuticals
JZP-386

March 2003
Jazz
Pharmaceuticals
Founded

February 2007
Licensed from
Solvay Pharmaceuticals



June 2012
Acquired
EUSA Pharma



Expect to close 1Q14
Acquisition of Gentium

Defitelio™

New Addition to our Commercial Portfolio

NARCOLEPSY

XYREM
(sodium oxybate) oral solution

HEMATOLOGY/
ONCOLOGY

Erwinaze
asparaginase
Erwinia chrysanthemi

Erwinaze
CRISANTASPASE

Kidrolase
ECCOLI-ASPARAGINASE

Defitelio
(defibrotide)

PAIN

PRIALT
ZECONOTIDE
INTRATHECAL INFUSION

PSYCHIATRY

FazaClo
(clozapine, USP)
Orally Disintegrating Tablets

Versacloz
(clozapine, USP) Oral Suspension
50 mg/mL

- Debilitating and complex conditions impacting small patient populations
 - High unmet treatment needs
 - Treated by a small number of physicians
- Physician education by Medical Science Liaisons and Specialty Sales
- Require patient support services and monitoring for safe and appropriate use

Our International Footprint

More than 700 employees* in 12 countries worldwide.

Distributing specialty pharmaceutical products in the United States and, through our international division, in multiple markets outside of the United States.



Headquarters:
Dublin, Ireland

Multiple Offices, including:
Palo Alto, CA, U.S.A.
Philadelphia, PA, U.S.A.
Oxford, U.K.

*As of October 2013. For more information go to www.jazzpharmaceuticals.com

International Commercial Platform Provides Global Reach

Direct presence in 10 EU countries & Canada

- Significant in 6 major EU markets (UK, Germany, France, Netherlands, Spain, Poland)
- Current infrastructure includes 40 sales representatives, 18 Medical Science Liaisons

Indirect (Commercial Partners) extend the international reach to over 80 countries

- Strong relationships built over many years
- Agreements can easily accommodate additional products
- Ability to easily move to Direct Infrastructure given a strategic rationale



Defitelio – A compelling proposition



Patient Benefit:
Life Threatening Condition = High Unmet
Medical Need



Unique product

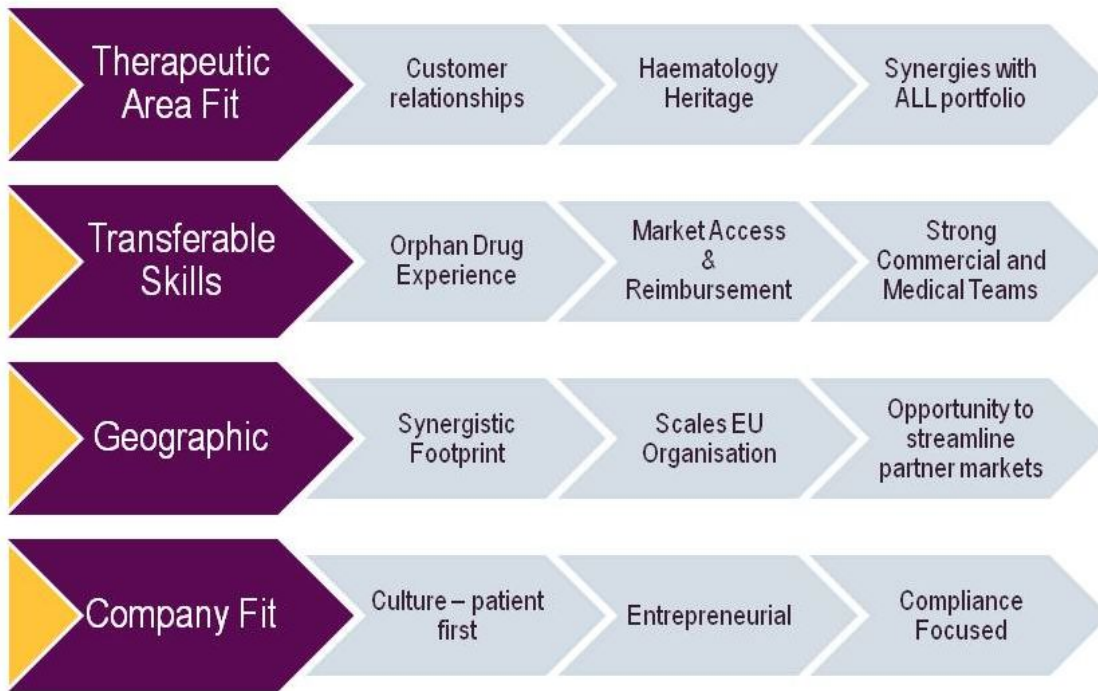


Focused Target Physician Group



Approved in EUROPE with considerable
named patient experience

A Compelling Fit With Jazz Pharmaceuticals



Working Together to Realise Our Mission Statements

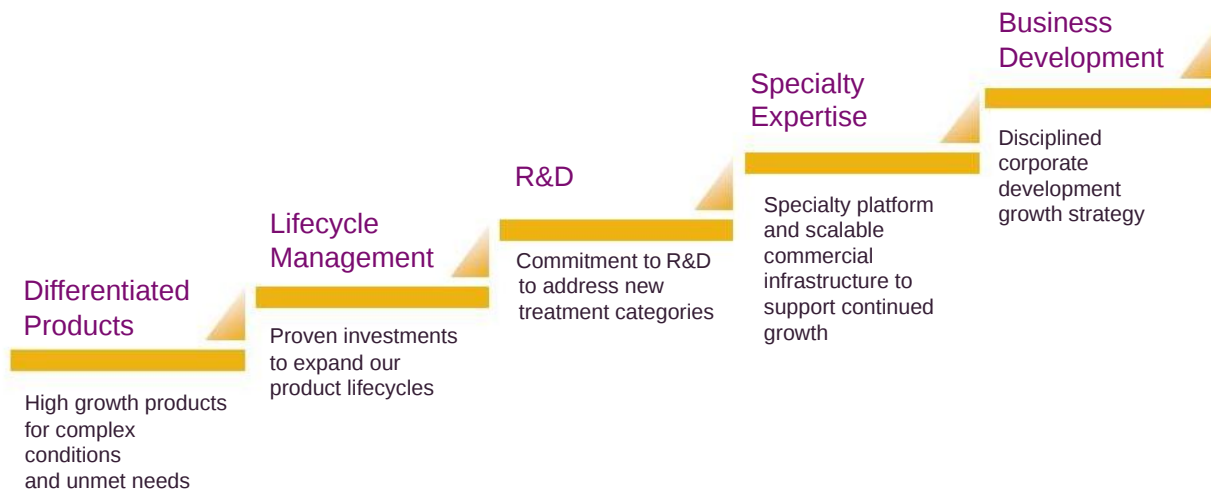
- Mission statements point to improving lives of patients with high unmet medical need
- Integration of the Gentium team
- Together Jazz and Gentium can optimise the launch of Defitelio



Jazz Pharmaceuticals is a dynamic specialty biopharmaceutical company that identifies, develops and commercializes innovative products to address unmet medical needs in focused therapeutic areas, always keeping in mind our mission to improve patients' lives.

Focused on Life: Providing new therapies to care-givers for diseases that currently have few or no treatment options with the aim to improve the lives of those faced with rare diseases with high unmet medical needs.

Execution, Growth and Long-term Value Creation



Our Growth Strategy: Business Development

Strengths

- Nimble, entrepreneurial organization
- Demonstrated commercial success
- Experience with complicated, “high touch” products
- Strong balance sheet
- Disciplined approach to resource allocation

Top Priorities for Review

- Currently marketed or close to approval
- Important unmet needs
- Targeted to specialty audiences
- Meaningful exclusivity
- Attractive financial return



Our Growth Strategy: Research and Development

Our development pipeline projects include line extensions for existing products, the generation of additional clinical data for existing products, and clinical development of new product candidates.

NARCOLEPSY

- JZP-386: Pre-clinical

ONCOLOGY

- IV administration: PK study
- Adolescents and Young Adults (AYA): PK study
- Pegylated recombinant *erwinia* asparaginase: Phase I (EU)

OTHER

- Anti-CD25 monoclonal antibody for the treatment of steroid-refractory acute graft vs. host disease: Phase III (EU)

*For information on products marketed in each of these therapeutic areas go to www.jazzpharmaceuticals.com

Additional Information

The tender offer for the outstanding shares of Gentium S.p.A. (including those shares represented by American Depositary Shares) referenced in this presentation has not yet commenced. The statement in this presentation is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Gentium, nor is it a substitute for the tender offer materials that Jazz Pharmaceuticals and its acquisition subsidiary will file with the U.S. Securities and Exchange Commission (the "SEC") upon commencement of the tender offer. At the time the tender offer is commenced, Jazz Pharmaceuticals and its acquisition subsidiary will file tender offer materials on Schedule TO, and Gentium will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. The tender offer materials (including an Offer to Purchase, a related Letter of Transmittal and certain other tender offer documents) and the Solicitation/Recommendation Statement will contain important information. Holders of shares of Gentium are urged to read these documents when they become available because they will contain important information that holders of Gentium securities should consider before making any decision regarding tendering their securities. The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Gentium at no expense to them. Investors and security holders may obtain free copies of these documents (when they are available) and other related documents filed with the SEC at the SEC's web site at <http://www.sec.gov> or by (i) directing a request to Jazz Pharmaceuticals plc, c/o Jazz Pharmaceuticals, Inc., 3180 Porter Drive, Palo Alto, California 94304, U.S.A., Attention: Investor Relations, (ii) calling +353 1 634 7892 (Ireland) or + 1 650 496 2800 (U.S.) or (iii) sending an email to investorinfo@jazzpharma.com. Investors and security holders may also obtain free copies of the documents filed with the SEC on Jazz Pharmaceuticals' website at www.jazzpharmaceuticals.com under the heading "Investors" and then under the heading "SEC Filings."

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Jazz Pharmaceuticals and Gentium file annual, quarterly (except in the case of Gentium) and special reports and other information with the SEC. You may read and copy any reports or other information filed by Jazz Pharmaceuticals or Gentium at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Jazz Pharmaceuticals' and Gentium's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at <http://www.sec.gov>.



Jazz Pharmaceuticals®
Innovation that performs