

Moderator: Ladies and gentlemen, and welcome to the Epigenomics Analyst and Investor Conference Call regarding the results of the second quarter and the half year 2017. At this time, all participants have been placed on a listen-only mode. The floor will be opened for questions following the presentation. Let me now hand the floor over to Mr Peter Vogt.

[00:00:25.16]

Peter Vogt: Thank you, Beatrice, and thank you everyone for joining Epigenomics conference call on our 2017 Q2 financial results. Detailed information on our financial results was released this morning and is available on our company website. During today's call we will make forward-looking statements based on current expectations. Our actual results may differ materially from such statements. My pleasure now to hand over to the company's CEO, Greg Hamilton. Greg, please go ahead.

[00:00:59.15]

Greg Hamilton: Thanks, Peter. Good afternoon everyone, and thank you for joining in our Q2 2017 earnings call. The focal point of Q2 was the voluntary takeover offer by Summit Hero Holdings of €7.52 per share. Regretfully, the minimum acceptance threshold of 75% was not met; therefore the takeover offer failed. As was to be expected, our stock prices subsequently dropped by over one third. Now the company has turned our attention to securing the robust financing necessary for Epigenomics to create long-term shareholder value. For Q2 the revenue was €246,000, an 80% decrease from Q2 prior year. The decrease is due to stocking effect of Polymedco's initial orders post FDA approval. 2017 revenue and test volume continue to be challenged by the current Medicare list rate and lack of Medicare coverage in the United States. Our adjusted EBITDA of €-3.4 million was in line with prior year. The net loss for the quarter was €-4.1 million compared to €-3.3 million for Q1 2016. The difference was mainly due to the share-based compensation payments. Correspondingly, the cash consumption in the quarter was €3 million compared to €1.9 million in the previous year. Cash consumption is in line with adjusted EBITDA. Epigenomics ended Q2 with €7.7 million in cash and marketable securities. We expect a convertible bond that was part of a tender offer to be executed this quarter. The additional cash from the convertible bond will be approximately €6.5 million, thus bringing the total available cash balance to approximately €14 million. This provides a cash reach in Q3 2017. Epigenomics is now exploring additional financing options to add the robust capital needs required to successfully commercialise Epi proColon and develop our deep pipeline of other liquid biopsy tests. On Monday we released an ad-hoc regarding the cumulative loss of more than half of the nominal share capital. This announcement was a statutory requirement and it does not reflect any further capital market transactions that we have consistently discussed as required for the long-term success of Epigenomics. In early July we adjusted our outlook for the second half of the year. Due to the fact that

revenue remains below expectations in the first half of 2017 and the fact that there will most likely be no Medicare reimbursement in the US market for the remainder of the year, we now expect revenue to be between €1 million and €1.5 million for fiscal 2017. Based on the reduced revenue forecast, the adjusted EBITDA is now expected to range between €-12.5 and €-14 million euros at the end of the year. With the failure of the tender offer we have now shifted our focus to securing the robust funding required for Epigenomics to achieve long-term shareholder value. We're validating all financing or strategic options for the company. Operationally, the three key areas of focus for 2017 continue to be reimbursement, guidelines and launch of Epi proLung. We believe we are making progress with reimbursement and expect some clarity in this area prior to year-end. However, as the reimbursement process is complicated, we cannot guarantee this timing. As we have discussed numerous times, commercial penetration in the United States is directly correlated with reimbursement, specifically Medicare reimbursement. We therefore believe significant commercial ramp will be possible after this milestone is achieved. Guideline inclusion is also an important factor in reimbursement and commercial ramp. As with reimbursement, we are committing significant resources to guideline inclusion. In regards to new products, we are on track to provide CE marking for Epi proLung by year end. Epigenomics has a large opportunity in front of us. We need the capital necessary to realise this opportunity. We have always viewed 2017 as a transformational year for the company, as we secure the resources necessary and achieve critical milestones such as reimbursement for the long-term success of the organisation. Thank you for joining our Q2 earnings call. I will now open the call for questions.

[00:06:24.18]

Moderator: Ladies and gentlemen, if you would like to ask a question, please press 9 and the * key on your telephone keypad. In case you wish to withdraw your question, please press 9 and the * key again. Please press 9 and * to state your questions. And the first questioner is Marietta Miemietz from Equinet.

[00:06:54.03]

Marietta Miemietz: Yes, good afternoon and thanks for taking my questions. I've got a number of reimbursement and the financial dynamics. So can I infer from your comment earlier that you basically expect to get a positive reimbursement decision by year end, which would imply reimbursement from the middle of 2018, so that's your base case scenario? Is that correct? And what do you think are the [unclear 00:07:22.13] factors that will determine when you actually get a positive reimbursement decision? I also wanted to ask about financial dynamics before and after reimbursement. Would you say that the Q2 sales that we saw are a run rate until reimbursement is granted, or do you expect to get some meaningful uptake in the private sector before that? And once Medicare starts reimbursing the test, how

long do you think it would take from that moment until you could finance your operations out of cash flow as access to external capital was limited? And then somewhat related, a question on your cash reach guidance. You've been very clear in the past that you need to invest heavily into marketing to push Epi proColon to its potential. So presumably a cash reach guidance to Q1 and Q3 2018 actually includes quite a bit of discretionary span that you could reduce if it became necessary to ensure the viability to 2019 and beyond, so can you give us a sense for the maximum cash reach if you were to decrease your monthly cash use to the bare minimum, and how fast do you think you could actually curb down spending levels if it became necessary?

And then I just have a bunch of more technical questions around viability. The question on the Capex-specific convertible, is that really completely in the bag, or could any circumstances arise that could allow Capex to pull out, and can you just remind us of the conditions? And is there any risk at all that you could be breaching any financial or operational cap covenants, including anything that could impact on your agreement with Polymedco?

And then just my final question, just to be 100% sure, that last notification that you had to do under German law because half of your nominal capital has been consumed, that's really just a technical thing and it will not affect the viability of the enterprise in any way, so you do have the cash reach until 2018, and with the Capex available you should be able to repair that technical issue of the diminished nominal capital very shortly, is that correct? Thank you very much.

[00:09:48.15]

Greg Hamilton: Thank you so much, Marietta. I might need you to repeat some of those questions; I will try and get to all of them. So I'll start on some of the last questions first. The convertible bond that was part of the tender was agreed as part of that process, and we see no risk to executing now, we are in that process now of execution. So we have very, very high confidence that we will close, there is nothing that we know of that would prevent that from happening. So that would add that cash to the balance sheet and extend our reach. In regards to the nominal capital and the issuance of the ad-hoc you're absolutely correct, it is a statutory requirement, it is based upon the book value of equity, not the market value of equity or our ability to raise financing. So it is just a statutory requirement that we had to do. That's the answer in regards to those two questions. In regards to cash, we...

[00:11:01.24]

Marietta Miemietz: Can you just remind us of the terms for the convertible as well?

[00:11:07.17]

Greg Hamilton: It is backed by a certain number of shares that was listed in the tender documents. So the term of the convertible is to the end of 2018, by that time or previous to that the holder of the bond in essence can convert into equity.

[00:11:37.12]

Marietta Miemietz: Okay, thank you.

[00:11:41.19]

Greg Hamilton: And then in regards to cash reach, the cash reach in 2018 is actually based upon our current cash consumption rate. We would be challenged to significantly reduce our cash burn to extend run rate beyond that, and we are a pretty lean organisation as it is, and we have certain obligations going forward. So for example we have the post-approval study as part of our PMA, we are required to continue to operate that study as a part of our PMA approval. So, you know, we do have some levers to minimise cash burn, but from a material perspective, you know, we would be challenged to really push it out much longer than that. So we've always been clear to everyone that the company is in growth mode, we need the capital to grow, and that has just been reflective of any company that has been successful in the cancer diagnostics space in the US, has ultimately been well capitalised to achieve those opportunities.

[00:12:59.18]

Marietta Miemietz: That's very clear.

[00:13:03.01]

Greg Hamilton: In any regards, if you could repeat some of the other questions, I want to make sure I get to all of them.

[00:13:09.22]

Marietta Miemietz: I just quickly want to make sure, so you are not at risk of breaching any covenants or any sort of other agreements with Polymedco where they would say, okay, if there is no reimbursement by such and such date or, you know, you are not...

[00:13:27.17]

Greg Hamilton: We are not in jeopardy of breaching any covenants that we're aware of, so again, the company and our partners realise that we need to raise capital to

seize the opportunity, and all of them have been very supportive in that endeavour, but we are not in jeopardy of breaking any covenants that we're aware of.

[00:13:55.08]

Marietta Miemietz: Okay, great, thanks. I think the rest was really more around, like, the operational performance or the reimbursement. So I got the sense that you were sort of expecting this year or by year end that you would get reimbursement within six months, i.e. your base case for reimbursement in mid-2018, is that correct, and what are the [unclear 00:14:16.02] factors for that? And then, I mean, once you do get that reimbursement, you know, how fast do you think you could actually get to the point where you can finance your operations out of cash flow, and what is a reasonable run rate until you get that reimbursement? So just to help us a little bit with our modelling, really?

[00:14:35.28]

Greg Hamilton: Yeah, so I think your assumptions in regards to reimbursement, you know, those are the timelines that we are identifying with. We obviously would like to secure reimbursement as quickly as possible. As we discussed, there are two methods; an NCD approach which is a national coverage determination, also legislation. So just based on the inherent nature of those two, we would hope to have clarity in either one of those areas by year end, which, you are correct, there's about a six-month lag then between once we get that clarity to actually reimbursement kicking in. So that would be around mid-2018, you know, assuming obviously we get that clarity by the end of this year. And then once we get reimbursement, reimbursement kicks in, you know, we do believe that we will see significant commercial ramp. As to when we would be able to basically stabilise the business from our own cash flows, that's to be determined and also is dependent on the amount of money we invest in that initial commercial ramp, because reimbursement allows us to go full-steam into marketing the product and, you know, we might be better off in the early stages investing heavily in the brand, the brand awareness, to create the greatest amount of long-term shareholder value sales. So, you know, we would be too premature to say when we think that timing would be, but we do think the opportunity is absolutely significant. I mean, as you know, there is anywhere between 25 to 30 million patients on the end screen market, so there is a big upside to, once we get reimbursement, to, you know, gain market share amongst those patients.

[00:16:43.24]

Marietta Miemietz: And would you say until you get reimbursement, what we've seen in Q2 are kind of your run rates in terms of sales and in terms of profitability?

[00:16:55.11]

Greg Hamilton: Yes, and the reason is the very interesting dynamic in regards to reimbursement. So if we push the product from a commercial standpoint significantly without reimbursement, you run the risk of backlash from physicians who order it, because they order the test for a patient, the patient gets the test, and it's not reimbursed, the patient calls up the doctor's office and complains. And that is the number one issue with ordering physicians, that they don't want to take those calls. It disrupts their practice, and then it affects their future ordering pattern. So you are in this position that until you get reimbursement you are challenged on really pushing the product. When you introduce it to a physician that orders the test, typically their first question is, is it reimbursed. So we understand that today, we are seeing sample volume growth, which is great, so that's happening in spite of not having reimbursement, which means the patient potentially has to pay cash for the test. I mean, there is demand for it already, but again, you do not see significant commercial ramp in the United States until reimbursement is in place.

[00:18:22.26]

Marietta Miemietz: That's very clear, thank you very much.

[00:18:26.08]

Greg Hamilton: Thank you, Marietta.

[00:18:28.06]

Moderator: Next up is **Wilhelm Zours** from **Deutsche Balaton**.

[00:18:34.29]

Wilhelm Zours: Hello, I have some questions regarding the actual finance situation right now. So this conversion note you want to place now, is it unchanged with the conditions like in the document, the offer document? So it's not adjusted to the lower share price we have now? This is one question. I would like to know whether you have been approached by other parties for takeover talk after this last one failed, and how is your contact now to Cathay Fortune? Are you in talks with them to do the same thing like with [unclear 00:19:21.03], so the second try again with Cathay Fortune, what do they say to you or what did you say to them? And what is the possible outcome of the reimbursement decision? So is it just yes or no, or are there any options in between this? What are these options, and what is the most likely one from your point of view? And I would like to know how big is the market without reimbursement? So if you assume the worst case, what would it mean for the company and for the market in the US? I also would like to know whether there are

any plans for the Chinese market, because obviously Cathay was interested also in the Chinese market, and what is the capital need to break even if we assume different reimbursement decisions? So maybe you can say in the worst case we have this and this capital need to break even, and this would be the path we would go, or in the best possible outcome, if we get a decision this year for full reimbursement, how much would be the capital need in this situation? Thank you.

[00:20:36.15]

Greg Hamilton: Thank you for the questions, I will try and make sure I answer all of them. In regards to the convertible bond, yes, the terms are exactly the same as in the offer document, so the amount of cash we receive up front is not connected to the current share price, it is a fixed amount. In regards to our relationship with the bidder, we have a very positive relationship with the bidder, the bidder has actually put out a press release on the Summit Hero website, you know, obviously stating that they are a significant shareholder in the company and they are still supportive of the company. However, anything beyond that is ultimately determined by the bidder, is not necessarily determined by us, and so therefore we have no comment on anything in the future in regards to Summit Hero, as that's the determination made by them. And then in regards to reimbursement, Medicare reimbursement ultimately is binary. We either get coverage or not. There are multiple methods to get coverage, so a national coverage determination issued by CMS or legislation are the two paths that we have to achieve that. So there is no in between in regards to Medicare. Medicare are 50% of our available market. The other 50% is covered by private insurance. We do have some private insurance companies that are covering the test right now. We see other private insurance companies that are not. That is a very standard process for a new test introduced into the US market, and it takes time then to get a vast majority of those private insurers to pay. But that process is pretty normal course. So ultimately, you know, what is the outlook for the company without Medicare reimbursement? It is more challenged because it is 50% of the available market by a single payer. In addition, many of the private insurance companies peg off of Medicare, both on rate and potentially coverage. So we do see it as a critical milestone for the company, and you would also look at that for any screening test for an eligible population, Medicare reimbursement is absolutely important for ultimate success. In regards to the prospects of the company without reimbursement, you know, we think it's a fantastic product, but ultimately you would be challenged to identify a successful print screening test for any other disease state that did not have reimbursement and was successful. [unclear 00:23:57.06] tests, yes, can be cash-based and be successful, but to have large-scale screening participation, reimbursement is going to be a necessary requirement in this market. Were there any questions I missed?

[00:24:16.04]

Wilhelm Zours: Thank you. To the first answer I have a question again. I did not ask for the amount of money you can raise with the conversion bond, I would like to know whether the conversion price remains the same. So of course you can raise 6.5 million if in exchange you have to offer now, let's say, 2 million shares with regard to the first, but you changed the conversion price because of the price of the shares has been lower now. So this still would mean you could get 6.5 million but you have to give more shares if it's converted.

[00:24:55.28]

Greg Hamilton: Yeah, the convertible bond has a fixed number of shares that are backing it.

[00:25:01.18]

Wilhelm Zours: So this means that the conversion price for one share, for the bond to convert the shares remains absolutely the same?

[00:25:09.09]

Greg Hamilton: No, there is a fixed number of shares and they are, you know, repayment is dependent on whatever the market price of the shares is at that time. And then if the number of shares do not cover the outstanding value of the bond, the company owes the difference as debt.

[00:25:33.17]

Wilhelm Zours: So this means the conversion price is determined by the conditions by the price when it's converted?

[00:25:41.04]

Greg Hamilton: Correct.

[00:25:44.22]

Wilhelm Zours: Are you interested to have other investors in this converted bond?

[00:25:50.11]

Greg Hamilton: This is already spoken for with the bidder, so we are both under the contractual obligation relative to this bond, and that was part of the negotiations for the takeover process.

[00:26:10.02]

Wilhelm Zours: Yes, but you couldn't read the counter value of the bond, you could say, well, we issued 10 million for this bond.

[00:26:18.07]

Greg Hamilton: Yeah, and we look at that as other financing activities, and as we said during the call, we're looking at all financing and strategic alternatives to raise the money necessary for the company.

[00:26:32.01]

Wilhelm Zours: Hm. Okay. And with regard to the answers for the reimbursement, I understand that Medicare is yes and no, and are there chances to go again to Medicare in two years or three years, or how long is it binding, this yes or no, and what do you need to go again to get another decision?

[00:26:55.07]

Greg Hamilton: There is no time limit on when a national coverage determination can be issued. So a national coverage determination could happen next month, it could happen four months from now, it could happen a year from now. So there is no time limit. And the same with legislation. So there is no absolute, that if it doesn't happen by this date it will not happen. That does not exist. So legislation, you know, a bill has to be passed by Congress, that's the process in the United States, and then in regards to the NCD, you know, we have discussed in the past that an NCD we believe is tied to medical guideline inclusion and, you know, those medical guidelines, there's multiple of them, and the timing on those guidelines vary from the issuer.

[00:27:59.03]

Wilhelm Zours: Okay, and the last question, which was, are there any plans for the Chinese market?

[00:28:05.04]

Greg Hamilton: Yes, we still have our strategic relationship with Biochain, so Biochain has licensed our product in China. They are going through the reimbursement process as well in China and are commercialising the test, and they have also licensed Epi proLung in China as well. So we do believe that the long-term market capability in China is significant, but as we've discussed for example at the AGM, for China, [unclear 00:28:40.13] and we get a royalty rate.

[00:28:45.14]

Wilhelm Zours: What is the best estimate for the decision in China, for the reimbursement there?

[00:28:52.03]

Greg Hamilton: Sorry, can you repeat that question?

[00:28:55.29]

Wilhelm Zours: What is your best estimate for the timing for the reimbursement decision in China?

[00:29:02.15]

Greg Hamilton: It's ongoing right now, so the reimbursement decisions in China are by province, unlike national reimbursement decision, a decision is the pricing you can charge in each province. So that takes some time. We are aware that our partner has gotten reimbursement in some of the provinces and is starting to commercialise in these provinces but has not achieved reimbursement in other provinces yet.

[00:29:33.28]

Wilhelm Zours: Okay, thank you.

[00:29:36.17]

Moderator: Next up is **Simon Scholes** from **First Berlin**.

[00:29:45.08]

Simon Scholes: Yes, good afternoon. You indicated in your response to the third question that there could well be a six-month time lag between a positive decision on coverage determination, either by NCD or by legislation. I was wondering if you can tell us what accounts for that time lag?

[00:30:07.03]

Greg Hamilton: For example on the legislation, it's written in the bill. The bill states that once it's signed into law that within six months Medicare needs to start reimbursing for the test. So that time lag is written into the bill, and you have to do that in the bills because you have to give CMS a certain amount of time to

operationalise the reimbursement. So they have to update their systems and their subcontractors and all of that, so that's why that's very standard course for legislation, that there is that time lag from approval until implementation. And an NCD can be fairly similar, so, you know, a process for an NCD can be, an NCD can be that an NCD application is accepted by CMS, they do a six-month review and then they implement. So that six months is pretty standard for the market.

[00:31:08.05]

Simon Scholes: Okay, thank you very much for that.

[00:31:11.02]

Moderator: At the moment there seem to be no further questions. For any additional questions, please press 9 and the * key. Please press 9 and * for any additional questions. And the next questioner is Sascha Zeiler from Knöten & Roge. It's your turn now.

[00:31:38.09]

Sascha Zeiler: Hi there, thanks for taking the question. One question maybe regarding the timing you expect for your refinancing. Would you rather like to wait until the decision is made on reimbursement in the US, meaning that a capital increase can be done thereafter, or would you also consider doing it before the decision has been made?

[00:32:01.13]

Greg Hamilton: We are looking at all options right now, including before the decision is made. We clearly would like to have more cash on the balance sheet right now, because we clearly believe that we need to start investing in the product, the commercialisation of the product, the branding, today to capitalise on the opportunity when reimbursement comes. We don't want to have to start that process after we get reimbursement because it just delays the timing for us relative to the size of the opportunity.

[00:32:39.15]

Sascha Zeiler: That's a good point. Another point would be of course that, let's say, after positive reimbursement you would get very much favourable terms on your capital increase.

[00:32:52.21]

Greg Hamilton: Absolutely, positive reimbursement determinations have a significant effect on the company, both in our access to capital and the amount of capital. We completely agree with that, so ultimately we think that the larger capital increases will be post-reimbursement, but, you know, there is definitely a place and the need for capital now as well.

[00:33:24.22]

Sascha Zeiler: Thanks a lot.

[00:33:26.29]

Moderator: There are no further questions.

[00:33:31.20]

Greg Hamilton: Thank you, everyone, for joining the call, and thank you for the questions today, and we look forward to updating you on our next quarterly call.