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SN.L - Smith & Nephew Acquisition Of Healthpoint Conference Call

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OVERVIEW:
SN.L announced that it is acquiring Healthpoint Biotherapeutics for $782m.
Olivier Bohuon - Smith & Nephew Plc - CEO

Good morning, everyone. This is Oliver Bohuon; I’m here with Roger Teasdale, our President of Advanced Wound Management, and Adrian Hennah, our CFO.

Welcome to our call to discuss the acquisition of Healthpoint, which we announced this morning. I will make some opening remarks and then hand over to Roger to talk about Healthpoint’s products and pipeline, as well as our integration plan. Then Adrian will take you through the acquisition numbers. As usual, we’ll take questions at the end.

Now starting with some details on Healthpoint itself. Healthpoint is a privately held advanced wound care Company, headquartered in Fort Worth, Texas. It is focused on the development and commercialization of novel, cost-effective bioactive products. This includes products for the medical removal of dead or infected tissues, so-called debridement, as well as skin repair and regeneration therapies.

The Company has a portfolio of marketed products which are forecast to generate revenues of around $190 million in 2012 and which are set to grow at a mid-teens percentage rate, going forward.
In addition to its marketed products, Healthpoint has strong R&D capability, [with] a lead product candidate entering Phase 3 clinical trials for the treatment of venous leg ulcers.

Healthpoint has approximately 460 employees. This includes a sales force of 215 who have strong and established customer relationships, and around 70 R&D staff.

As you know, one of Smith & Nephew’s five strategic priorities is supplementing our organic growth through acquisition. This is in order to continue investing and orientating our Company to higher growth areas to satisfy our determination to build significant value for our stakeholders.

When we look objectively at our Advanced Wound Management division, we see a strong growing business outperforming its market. In addition, for some time, we have believed that, as a leader in the wound market, we also must be a leader in the area of bioactives.

Through the acquisition of Healthpoint, and combining it with our Advanced Wound Management division, I believe that we will create a very powerful and unique offering in the marketplace. Healthpoint’s bioactive product range is very complementary to our wound care product and establishes Smith & Nephew Advanced Wound Management as the only wound business with genuine strength in exudate and infection management, negative pressure, and bioactive wound therapies.

Bioactive wound healing is now a major segment of Advanced Wound Management at an estimated size of around $1 billion, and it is also the fastest growing segment. This broad category of products includes those designed to enhance body natural healing processes and bioengineered products. As such, it will be an increasing feature of wound care in the future.

The acquisition will accelerate the growth rate of Advanced Wound Management, both from Healthpoint’s existing suite of marketed products and, in the longer term, from its pipeline. Its lead product candidate is entering Phase 3 trials and this will be to treat venous leg ulcers, which is a large potential market.

In terms of integration, Roger Teasdale will talk through our plan. Healthpoint already has a strong leadership team; we look forward to welcoming them to Smith & Nephew. This means we can carry out a gradual integration, ensuring minimal disruption to either Healthpoint or Smith & Nephew.

Healthpoint doubles our scale in the US where we are currently underrepresented, compared to Europe. Over time we believe that this offers many opportunities to expand and improve the combined US business. We are also acquiring a new R&D capability. As we progressively integrate the business there are opportunities for both revenue and cost synergies.

In summary, for Smith & Nephew to build this type of organization from scratch would have taken many years. The acquisition meets our strategic and financial criteria, and Adrian will detail the source of value. We are very confident it will exceed our cost of capital in the third full year following the acquisition, and will be broadly EPS neutral in 2013 and accretive thereafter.

I will now hand over to Roger to give you more details on Healthpoint’s products, pipeline and integration. Thank you.
Over a period of 2006 to 2010 we saw the normal advanced wound management market grow at a rate of about 6.5% compound, whereas the bioactives therapies grew at over 50%.

The bioactive products are also characterized by highly efficacious and proven clinical outcomes. They possess strong market access and payor coverage, and particularly in Healthpoint’s case, the products have very wide labels and applications.

Now let me introduce the key products, the key three products, and starting with the main product, Santyl. Santyl gained its biologic license in 1965. It’s a product that contains an enzyme, collagenase, in a petroleum base, and it’s the only FDA-approved enzymatic debrider. And just to restate what Olivier said, debridement is the action of removing the dead or necrotic tissue that can maybe inhibit wound healing.

Santyl is indicated for all chronic wounds, pressure ulcers, diabetic foot ulcers and venous leg ulcers, and also for severely burned areas. It possesses a strong evidence and safety profile, and has excellent reimbursement coverage in the US. We believe there are a number of market conditions that further support strong growth for the Santyl brand.

First of all, there’s further space to increase market penetration and geographic coverage as a sole reimbursed enzymatic debrider. Secondly, it’s a very simple and cost-effective clinical solution versus other forms of debridement, such as sharp debridement by the scalpel, or also autolytic debridement. And then, thirdly, we want to build and continue the strong work that Healthpoint have started in increasing the dosage of Santyl to more effective levels for the existing wounds that are being treated.

Turning to the second key product, Oasis, this is an acellular matrix skin substitute. It’s porcine derived, and it assists in the repair of damaged tissue for venous leg ulcers and diabetic foot ulcers. The product benefited substantially from changes in the reimbursement structure in the US at the beginning of 2012, and we believe there’s further strong growth potential of the product.

The last product on the page is Regranex. This is a product acquired from Johnson & Johnson in 2011. It has a strong sales history, and it’s a human-platelet derived growth factor to stimulate wound healing. It also has a biologic license, and is indicated for neuropathic diabetic foot ulcers. And this product will be re-launched in mid-2013.

Turning on to the next slide; we believe there are a number of compelling and attractive capabilities and opportunities with the transaction, and I’d just like to cover six key areas. First of all, it builds greater presence and scale in the US for Smith & Nephew. That allows for greater relevance to key opinion leaders, our customers, and also collaborators. In terms of scale, it takes our organization in the US from 260 people to over 700 people. And in terms of sales force, it more than doubles our sales force to north of 350 people.

It also provides for new channels. Healthpoint currently focus on winning clinics and position offices, where we’re not greatly focused at the moment. And they also provide a lot more focus on the long-term care sector which, again, complements the Smith & Nephew focus on acute care. They also possess very strong commercial capabilities built around detail account targeting and management, and a very strong commercial execution model.

The combination provides a varying compelling product portfolio, post closure, with market-leading exudate management products centered around ALLEVYN infection-management brands, such as Iodosorb and [Actico]; negative pressure with our RENASYS and our disposable negative pressure product, PICO; and now a range of bioactive products.

In terms of R&D, then again, we see strong attraction in terms of the R&D capabilities they bring into the bioactive space, built on strong skills developed over many, many years, particularly around four science platforms, cells, enzymes, matrices and growth factors. But also in terms of their process skills of exploration, discovery, and scouting for technology, and then being able to convert that through licensing, regulatory and IP skills.

This biological innovation very much complements the systemized new product delivery that Smith & Nephew have developed over 30 new products a year over the last four years or five years.
Turning to their pipeline and their flagship product, HP802, again we’re very excited about the potential for this product. Let me just, first of all, tell you a little bit about the product. It’s a cell-based therapy. Personally I think about it like a drug delivery system. It’s cells based in a fibrin gel, indicated for the treatment of venous leg ulcers. These are neonatal, fibroblast and keratinocytes which have been growth arrested, and applied via a spray mechanism. They secrete growth factors, recruit others, and speed up the healing phase.

Our excitement is based on very strong Phase 2b results, which met all primary and secondary end points. And the Phase 3 trial in the US has already started. We also see strength beyond 802 in the pipeline and we will continue to invest behind their R&D and science capabilities. Another product just to call out is their second-generation enzyme, which is more purified and more active than the current collagenase product.

Turning to the slide titled integration, then, as Olivier’s already referred to, we will aim for a phased approach of integration to maximize value to both companies, particularly whilst maintaining our top line focus. So in the near term, it’s business as usual for our two sales forces. We start from a very strong cultural start point, where a focus on the patient and innovation runs deep through both companies.

Healthpoint have a very strong market presence, excellent commercial execution, and it’s our intent to continue to invest and optimize our joint capabilities in North America and beyond. The headquarters will remain in Texas, with the concentration of the key activities.

We see a very complementary portfolio, so [not only] -- following debridement then Smith & Nephew offer a range of anti-microbials; Iodosorb, a product that used to be marketed by Healthpoint; and also Actico range of products. But then negative pressure and PICO tend to follow Oasis in many situations. And then, of course, we have a range of wound-covering dressings, such as post-operative dressings, that fit very well with the treatments.

Moving on down the page; over time, we will seek opportunities for synergies, particularly around back office, where we’ll provide services where the former parent, DFB, used to provide services and perhaps, given our scale, we can offer more efficiency; and then also through size, such as distribution efficiencies as well. We also will seek revenue synergies, particularly outside of the US. And just to finish with, we will maintain the pace of investment in terms of building the capabilities in their bioactive R&D, and maintaining the investment in the very important flagship product, HP802.

So in summary, I’m very excited by this opportunity. It builds significant scale in the strategically important US market. It adds strong commercial and R&D capability. It builds on our recent, strong, performance and the combination will create a formidable value proposition across the continuum of wound care.

With that, I’d like to hand over to Adrian, who will talk to the financials.

**Adrian Hennah** - Smith & Nephew Plc - CFO

Thank you. Thank you very much indeed, Roger.

Turning firstly to slide 12 in the presentation, a summary of the profit and loss account of Healthpoint. We’ve shown here the total revenue and trading profit of Healthpoint for 2010 and 2011. We’ve also shown the forecast revenue for 2012. Revenue in 2011 grew at 21% over 2010; and revenue in 2012 is forecast to grow at around 26% on 2011.

Santyl accounted for about three-quarters of the total revenue in 2011, and is growing strongly.

Trading profit was modest in 2011; $11 million, or a 7% margin. We have included a summary of the 2011 cost structure in the appendices. You will see that gross profit is strong, currently around 75%. Selling and administrative costs are, however, currently high, relative to sales, around 55%. This is a scale issue. As revenue grows, we expect significant operational gearing in this area. In addition, we see opportunities for cost synergies, and will return to this.
R&D costs are also significant, relative to sales, currently around 15%. The Healthpoint R&D model is essentially one of search and development, as opposed to research and development. There are, therefore, two main types of R&D cost.

Firstly, a relatively modest but important cost supporting the expertise to search for opportunities. Secondly, a higher cost to fund the development of products brought through into the pipeline.

As you have heard, 802 is the main product in the current pipeline, and it’s expected to be the principal driver of R&D costs in the near term.

Net operating assets at the end of 2011 were $61 million. We have set out a summary of the end 2011 balance sheet in an appendix. Inventory and property, plant and equipment account for most of the capital employed. The largest part of the acquisition costs will, therefore, appear as acquired intangibles and goodwill in our own balance sheet.

Turning then to the next slide, slide 13, and the summary of the transaction’s financials.

The purchase price is $782 million, payable on completion. There are no performance-related elements to the consideration. If completion occurs after December 31, 2012, an additional $10 million will be payable to the vendors. A significant sum will be held in escrow for varying periods, to support various warranties in the purchase agreement. The consideration will be financed from the Company’s cash balances, and from its existing borrowing facility; a $1 billion revolving credit facility, which runs to December 2015.

We expect the transaction to exceed our weighted average cost of capital in 2015, the third full year following the acquisition. We estimate our after-tax cost of capital at 8%. We expect the transaction to be broadly neutral to EPSA in 2013, and accretive thereafter, using a cost of borrowing of 1.5%.

The acquisition is structured as the purchase of assets, mainly in the USA. Accordingly, we will be able to amortize most of the cost of the acquisition against our taxable income in the United States over 15 years. This provides a material cash benefit to the Company. It will not show in earnings as, under IFRS, we are obliged to reserve for the benefit in deferred tax on the basis of a future disposal, or a notional future disposal of the acquired asset, with a lower base cost.

Turning to the next slide, slide 14. We expect cost synergies of around $20 million per annum after three years. This will come almost entirely from administrative and support costs. As Roger has explained, we will integrate certain [back office] administrative functions with S&N’s activities, and will integrate sales support activities over a slightly longer timetable.

We have included only very modest sales synergies in the financial model, single-digit millions of dollars. We expect integration cash costs of around $25 million over three years, plus probably some modest non-cash costs.

Turning to the next slide, slide 15, and our guidance on future financials for this acquisition.

Firstly, on revenue growth. As you have seen, Healthpoint sales are currently growing at around 25% per annum. We see mid-teens growth for several years. For 2018, we see significant potential for 802 to increase the top line, but this is, of course, dependent on progress with the product’s development.

Secondly, on profit; as we have mentioned, we expect significant benefit from operational gearing on the level of SG&A spend. With regard to R&D spend, we expect to invest materially in the development of 802. We expect a base level of R&D around $15 million per annum. On top of this, we expect to spend, on 802, an average of around $25 million per annum for five years, with a slight frontend loading.

In aggregate, R&D spend in the medium term will, therefore, be around $40 million to $50 million per annum. As we develop the potential in this area, we expect that R&D spend for the Group as a whole will rise slightly, but not greatly, above 5% of sales target that we have had in place.
Turning to the last slide in this part of the presentation, slide 16. This slide aims to summarize the main sources of value in the transaction, and among other things, therefore, give you a good sense of why we expect the transaction to provide a return in excess of our cost of capital in 2015.

We believe that Santyl, and its potential for expanded penetration in the existing marketplace, provides the single largest contribution. We also expect several other products in the portfolio to contribute meaningfully.

We see the potential for 802 to be a very major product, but also, of course, see risk, given the stage it is at in development, and the further cost to bring it to market. Taking into account these future costs, we attributed only modest value to the existing pipeline in our formal financial evaluation.

We believe that Healthpoint brings us important expertise with which to find and develop future bioactive wound products. We see this as very valuable, but have not attributed value to it in our financial evaluation. We see important, but modest, benefits from synergies, as you’ve seen, and we have already covered the material tax benefit offered by the structure of the transaction. Together, we see these elements offering a compelling financial rationale for this acquisition.

And with that, I will hand back to Olivier.

**Olivier Bohuon - Smith & Nephew Plc - CEO**

Thank you, Adrian. Thank you, Roger. So let me summarize. The acquisition of Healthpoint is an important step for Smith & Nephew, and for our Advanced Wound Management division, as you can have seen. Strategically, it gives us a very strong position in the fastest-growing area of advanced wound management, the bioactives. It does this by bringing us material revenue from a fast-growing product range, attractive pipeline, and the commercial and R&D capabilities upon which we will build.

The combination creates a wound business which is unique, having leadership positions across exudate and infection management, negative pressure, and bioactives. This acquisition, alongside our recent quarterly results and the dividend increase we announced earlier this year, demonstrate that our strategy priorities are creating value for our stakeholders.

Thank you very much, and that ends the formal presentation. We’ll now take questions.

**QUESTIONS AND ANSWERS**

Operator

Thank you. (Operator Instructions). Lisa Clive, Sanford Bernstein.

**Lisa Clive - Sanford C Bernstein - Analyst**

A few questions. Number one, on the Regranex product that I believe you said you’d bought from J&J, you mentioned the product would be re-launched in 2013. Could you just give us a brief history of -- I guess I assume it was in the market, and then withdrawn, just what happened there?

Second question around revenue synergies. Is it safe to assume that all the sales have been in the US to date? And if you could just explain a little bit your strategy for expanding internationally?
And then the third question is around your traditional wound management portfolio in the US. That’s an area where you’ve been -- had lower market share than you have elsewhere. And just wondering with now negative pressure wound therapy, and then this bioactives platform, how much of a real growth driver we could expect that to provide for your traditional Wound Management business in the US over the next few years?

Olivier Bohuon - Smith & Nephew Plc - CEO
Thank you, Lisa. Roger Teasdale will answer the first questions.

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Okay. On Regranex, just perhaps I confused you. It was bought by Healthpoint from Johnson & Johnson, so we’ve acquired it from Healthpoint. Just to give you a little bit of history; the product’s not been withdrawn from the market. It wasn’t the focus of J&J just before they sold it; they had other things to concentrate on. And then it hasn’t been the focus for Healthpoint over the last year or so, as they’ve grown the Santyl business.

So we believe it was a substantial product, well liked by physicians and clinicians in the market place. It certainly got to around $70 million to $80 million sales historically, and we have high hopes for its growth in the future.

Olivier Bohuon - Smith & Nephew Plc - CEO
Good. And so revenue synergies, so I think that I said this morning that the synergies can come from two places. The first place is the US. Again, we are increasing our sales force, going from roughly 150 reps to something like 360-plus reps. So we believe that we will have synergies in the future there.

Then we have the development of [international], which is also something that we can capitalize on, and this will be important. So Roger, you want to --?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Yes. I think just to build on Olivier’s point, then; a number of the products are registered outside of the US, and clearly, we have a very strong presence in Europe and in Asia-Pacific, and we would look to build up on that strength with those products.

Lisa Clive - Sanford C Bernstein - Analyst
Okay, great. So just on Regranex, so just to specify, the product has always been in the market; when you talk about re-launch you just mean sort of redoubling efforts to get that product really out there and marketed properly?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Absolutely. I think we just -- it’s all about focus, and also about the positioning of the product.

Lisa Clive - Sanford C Bernstein - Analyst
Okay. Thanks very much.
Operator
Martin Wales, UBS.

Martin Wales - UBS - Analyst

One historical question first. Obviously, Smith & Nephew used to sell Santyl up to the end of 2003, when Abbott manufactured it. Could you just take us through what’s happened since then that’s made this product so much more attractive and such a strong growth business today?

Secondly, I’m just trying to understand the timeline for HB802. My understanding is the Phase 3 trial, at least, that listed on clinicaltrials.gov, should complete in middle of 2014. You’re talking about a 2017 launch; maybe you could take me through what needs to be done to get this product approved?

And I guess, as a corollary to that, could you address how confident you are that you can manufacture this product reproducibly? The efficacy and safety looks very good in the Phase 2 study, but I’m guessing manufacturing of such a complex product is, of itself, very complicated.

Olivier Bohuon - Smith & Nephew Plc - CEO

Yes, let me share the answer with Roger, but let me just say something on Santyl. Just look at the results of Santyl and the growth of this product during the past years, which is a strong double-digit growth. We now reach almost $160 million, I forgot the exact number, Roger, of Santyl, so it’s not at all the same situation than in 2003. So I think it’s a very important thing to consider. They have been very successful with this product.

We believe that we can be even more successful with this product because of the strength of Smith & Nephew now that we have in the US. So we are very confident in our ability to be successful with Santyl. We also are very confident that the power of Smith & Nephew and the brand equity of Smith & Nephew in the US is definitely a big plus for such a product.

So, Roger, do you want to take the rest of the question?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Well, let me just add a little bit of color to the history, because I certainly was at Smith & Nephew during that time. So you correctly state that Smith & Nephew used to distribute the product up to 2003. The brand was owned by Abbott, and I think we felt the brand was extremely attractive at that time, as we still do.

What stopped us marketing the product was actually product supply issues, so the main manufacturing source in Curacao was owned independently and had a number of issues. Subsequently, that was purchased by Healthpoint, so new owners and they, through significant capital investment and focus, corrected all the manufacturing issues.

So we feel very confident and, as you can see from the track record of growth, product supply has been very stable and, therefore, we feel very confident in terms of acquiring this product and being able to market it successfully at this stage.

Olivier Bohuon - Smith & Nephew Plc - CEO

And there was a question on the replicability of 802.
Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Yes, okay. In terms of 802 manufacturing then, currently the products made for the clinical trial, the Phase 3 clinical trial that started in the US are made in Lausanne in Switzerland. There, Healthpoint have a dedicated team focused to the manufacture, a very capable team and, again, we have a great deal of confidence in that team.

In parallel, a facility is currently being built in Texas to replicate that facility. External skills have been brought into Healthpoint to build that capability, and that will be built in parallel. It's likely that the second Phase 3 trial will -- the product will be supplied from there prior to launch.

So I think we have every confidence in the science and the application of our science into live manufacturing processes with Healthpoint.

Martin Wales - UBS - Analyst

So you've answered part of my other question about why it's going to take 'til 2017 to get this product to market. There's one Phase 3 trial listed on clinicaltrial.gov. Are you going to run a second trial from the sound of things, which I guess you have to?

Olivier Bohuon - Smith & Nephew Plc - CEO

Well, yes. Actually, we have finalized in August the Phase 2b trials. We are now entering in Phase 3; we start to recruit the patients. As you know, it will take a while and so we plan to end these clinicals in 2017 and launch immediately after.

Martin Wales - UBS - Analyst

Okay. And just one follow-up on Regranex before I get back in the queue. You're talking about putting more effort behind the product. Is there anything you can do about the black-box warning? It seems to have increased rate of mortality secondary to malignancy.

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Yes, you're absolutely correct. Regranex was given a black-box warning, so this was regarding three doses with the potential of increased mortality secondary to malignancy.

We believe that, first of all, the product has a very strong profile and very strong clinical preference, even with the black box. At the same time, the black-box label was actually issued partway through a study, a long study, multiyear study. When that study actually completed, it actually didn't show any evidence of increased mortality. So it was an interim finding that was subsequently disproved in the final report.

So we do think there's a good chance in terms of being able to discuss the black box, the scope of it and the applicability to Regranex. That said, we still remain very confident about the positioning of the product with the appropriate marketing and commercial support in terms of driving the sales.

Martin Wales - UBS - Analyst

Okay. That's very clear. Thank you very much.

Operator

Veronika Dubajova, Goldman Sachs.
Veronika Dubajova - Goldman Sachs & Co - Analyst

I have three questions, if I can? The first one is on 802. Maybe you can walk us through if the clinical profile of the product is comparable to what you saw in Phase 2 and you are able to successfully replicate the manufacturing, what kind of market potential do you think realistically we should have in mind within five years from the product launch in 2017?

My second question is just a quick financial question. Adrian, if you could clarify what type of cost of debt do you have on that credit facility that you will be using to finance this?

And my last question is a bigger picture question. You've highlighted that you expect this to exceed your cost of capital within three years, but arguably, this business is slightly more risky than the rest of your portfolio. So I'm wondering how are you thinking about bringing that incremental source of risk in terms of this being more of a pharma-type of a portfolio as opposed to medical device one. Why did you decide to pursue an acquisition that had a slightly different risk/reward profile, relative to the rest of the business?

Adrian Hennah - Smith & Nephew Plc - CFO

Well, this is the second one, obviously, the cost of debt. The cost of debt, we have -- our revolving credit facility is very low cost, it's -- I forget the exact basis points above LIBOR and it does vary depending on where we are exactly in the billion, but it's very modest, 50/75 basis points level. I can't remember the exact number, but it's very modest indeed, Veronika. In modeling the accretion dilution of 1.5%, we were being very conservative.

Veronika Dubajova - Goldman Sachs & Co - Analyst

Okay, that's great. Thank you.

Olivier Bohuon - Smith & Nephew Plc - CEO

And the risk profile, it is marginally changed. Frankly, I don't think that it changed significantly the risk profile of the Company, because we have one product in R&D which has to be developed. Entering into Phase 3 was [excellent as far as], Phase 2b, so I'm really not very concerned about the risk profile of Smith & Nephew, which is not changing actually.

Veronika Dubajova - Goldman Sachs & Co - Analyst

And any thoughts on how significant 802 could be?

Olivier Bohuon - Smith & Nephew Plc - CEO

Well, Roger, do you want to take that?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

I think the way we think about it is, we see over 1 million venous leg ulcers in the US market, and we believe this product has the opportunity to get a substantial portion of this market.
Adrian Hennah - Smith & Nephew Plc - CFO

There’s no doubt, potentially this marketplace is very big, but equally, it’s 2017/2018 and there’s a lot of risks in the development pipeline. So in terms of our financial evaluation, Veronika, we haven’t put a lot around it, and we would urge you to be just as cautious in thinking about it.

But in terms of potential, it’s clearly very large. This is a very substantial market, growing fast, underserved, so the commercial evaluation [of the factors is you may] get some very big ticks when you look into it.

Let me just add a little bit on your risk question if I may, Olivier, because it’s a good question, Veronika. There’s no doubt that the nature of the pipeline of Healthpoint, in terms of the length of time it takes to bring products to market, that the risk of them falling over on the way and the cost of getting it from A to B is different from the traditional profile of what we do. There’s no doubt about that.

Why are we doing it? Well, we’re following the technology and we’re following the customer need in the marketplace in which we are the number one biggest player. So it’s absolutely the sensible thing to be doing.

Does it change materially the shape of the business? No, it doesn’t. It’s a small item. It may be a pointer to a direction we go in the future.

Very specifically, in terms of financial metrics, does it change materially our guidance for R&D spend as a percent of sales? No, we have -- in our prepared remarks, we suggested there will be a slight upward tick.

Obviously, there will be if we’re spending $40 million to $50 million in this area and bringing in $190 million of revenue, albeit fast-growing revenue. So clearly, there’s going to be a marginal upward tick, but we do not see this as anything more than a minor evolution in that direction. But it is an evolution in that direction.

Olivier Bohuon - Smith & Nephew Plc - CEO

And I would say it’s an essential evolution because again, if you’re not there, you’re nowhere in the future of the wound management.

And again, you also have to understand, we’re not talking about pills here or injectable products. We talk about a spray for the 802 and ointment for Santyl, so it’s not at all the same type of profile in what you can have in a pharmaceutical area.

Adrian Hennah - Smith & Nephew Plc - CFO

Yes, and very much addressing a complex channel in which we’re very expert.

Veronika Dubajova - Goldman Sachs & Co - Analyst

Okay, that’s very helpful. Thank you very much.

Operator

Ingeborg Oie, Jefferies.

Ingeborg Oie - Jefferies & Co - Analyst

The first one, I didn’t quite catch what the present value of the cash tax benefits that you were expecting to get in the US was. If you could just give the total number that you estimate, that would be very helpful.
Second question is, what headroom do you see this leaving you after paying for the acquisition? What would be your further appetite for some more acquisitions after this?

And then I just wanted to clarify when you said that this should accelerate the growth in the Wound division, that that takes into account the weakening environment that you have talked about in Europe, with further pricing pressure and maybe also that with the more sizeable -- size of the negative pressure wound care business that that growth driver may be slowing.

Olivier Bohuon - Smith & Nephew Plc - CEO

Hi, Ingeborg, it's Olivier. Yes, it will accelerate definitely the growth of the advanced wound management. We are entering here a business which, as we said, is in the mid teen, going forward, in terms of growth, plus the potential of the market, which is definitely huge now, and entering with the 802 in the venous leg ulcer business, which as mentioned by Roger, is about $1 billion now -- sorry, 1 billion leg ulcers in volume. So it's definitely a huge risk factor to be in this business.

Second part of your question regarding the headroom for acquisition. Well, look, it's a significant acquisition, obviously. We still have, as you know, an appetite, but we are very careful in what we do here.

We have said clearly that we are going to review with our shareholders and investors the balance sheet in the first half of 2013. We'll do that and we'll see, at this stage, where we stand.

Adrian Hennah - Smith & Nephew Plc - CFO

And, Ingeborg, to your first point, you didn't miss what we said for the present value of the tax benefit. We didn't give it to you, but we have, hopefully, given you enough calculations to calculate whatever you want.

I just repeat the key elements of them, Ingeborg. We're buying assets in the United States; the bulk of the $782 million, not 100%, but the bulk of the $782 million acquisition cost will be depreciable against tax in the United States. So you take something a little less than $780 million, say, $700 million, divide by [15] and that amount can be deducted from taxable income in the United States. We have a corporate marginal tax rate in the United States, much as everyone else does, in the high 30%s, 38-ish%. And that's the tax benefit; it's not trivial.

Ingeborg Oie - Jefferies & Co - Analyst

Great, thank you.

Operator

Navid Malik, Cenkos Securities.

Navid Malik - Cenkos Securities - Analyst

Just on 802 again, if you look five years out into 2017, the competitive environment within regenerative medicine and cell therapies will start to get pretty exciting, because there are a number of products which will we'll be potentially launching into this space, into the wound care venous leg ulcers and diabetic foot ulcer space, obviously complementing the acquisitions that Shire did with Advanced Biohealing last year.

I just wondered whether you felt that, five years out, that competitive environment might mean there are other opportunities you could move forward with in the cell therapy space to complement the product profile of 802, in particular any synergies that you might be seeing with other
Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Thank you for your question. I think the way you’ve laid it out is perhaps the way we’re seeing it. We actually see this as the fastest growing area of advanced wound management, hence the rational for the transaction. There are a number of products in the pipeline, as you say, probably three years to five years out, which we monitor very carefully. We believe this is the most compelling from our particular viewpoint and, at the same time, I think we still stay very open to looking for other opportunities and other synergistic opportunities as you outlined just, I think, underscoring the opportunity for these types of products in the future.

Adrian Hennah - Smith & Nephew Plc - CFO

And I think it’s worth adding, because you’re quite right, we do see the potential competitive nature of new entries that you describe, but there’s no-one else with the strength of a channel. It is a complicated channel; it’s not a straightforward channel at all. And it’s the combination of the channel we have with the access to these products that we find particularly exciting.

Navid Malik - Cenkos Securities - Analyst

So from the perspective of risk management as the manufacturing base is expanded into Texas, one of the issues, I suppose, is that living cell products are very complex to manufacture and expensive. And so I’m assuming that you’ll manage that expansion in a risk managed way to ensure that, if the trial is successful, you can benefit from it. But otherwise, obviously, if the trial weren’t to be successful you wouldn’t want to be spending a lot of CapEx, going forward.

Adrian Hennah - Smith & Nephew Plc - CFO

You’re quite right; there clearly are risk calculations, benefit calculations and there has to be some investment in risk through this. And obviously, it’s an area we’re looking at very carefully, just like everyone does who goes through these sort of processes.

Navid Malik - Cenkos Securities - Analyst

Okay, thanks a lot. Thank you very much.

Operator

David Adlington, JPMorgan.

David Adlington - JPMorgan - Analyst

Firstly on Santyl, I just wondered if you could pull out the percentage of sales that currently come from Santyl, and do you expect any competition to come in? Clearly, it’s been approved under a BLA, but just wondered what your thoughts were in terms of potential for competition there?

On Regranex, just wondered why you didn’t look at it when J&J sold it the first time around?

And then finally on HB802, for those of us with slightly longer memories, just wondered if you can compare and contrast that product with DERMAGRAFT and why you think this product is potentially better than DERMAGRAFT?
Olivier Bohuon - Smith & Nephew Plc - CEO

On Santyl we don’t see any competition for a while, actually. This is a good business; we have a very [clean and clear] environment there, so we don’t foresee any type of major issue in front of us.

Regarding Regranex, why didn’t we look at it, because we didn’t want to buy a single product. We wanted to buy a capacity of R&D and not to [play just with] one product, but to build our future.

Adrian Hennah - Smith & Nephew Plc - CFO

Three is over to you Roger.

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Okay, let compare and contrast 802 to DERMAGRAFT. I think, as you know, that DERMAGRAFT is only focused on diabetic foot ulcers, so this is targeting venous leg ulcers, a greater population, first and foremost. DERMAGRAFT and other competitor products use a scaffold in terms of holding the cells and, for example, if you did a biopsy a few weeks later you wouldn’t see any existence of the product.

The way to think about 802 is it’s more of a concentrated form, so the fibroblast and the keratinocytes are dosed in directly into the wound without a scaffold, and what we see is the speed of closure and the enhanced healing form that process. So I think significantly different in terms of its application, and also in terms of the results that we’ve seen in Phase 2B.

Adrian Hennah - Smith & Nephew Plc - CFO

And to your quantified question David, Santyl is around 75% of total sales of Healthpoint at the moment.

David Adlington - JPMorgan - Analyst

Great. Thank you very much.

Operator

Jonathan Beake, Citi.

Jonathan Beake - Citi - Analyst

Most of them have been answered; I just have one quick one. Just beginning of this year, you said it was an acquisition or potentially some sort of shareholder capital return. I was just wondering, can we assume that, now you’ve done this acquisition, that a capital return of some sort is unlikely in the next 6 months to 12 months?

Olivier Bohuon - Smith & Nephew Plc - CEO

I think I’ve said that; I thought it was clear, but again, we have not changed anything. We will review this in the first half of 2013; that doesn't change anything.
Operator

Julien Dormois, Exane.

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Jonathan Beake - Citi - Analyst

Okay. Thank you.

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Julien Dormois - Exane BNP Paribas - Analyst

I just have one question which relates to the potential of sales improvement over the next few years for Healthpoint, but also the synergies you might derive. You've indicated that you target mid-teens sales growth for the business; is that for the underlying business, and then, all the synergies like the ability to increase the sales in the other segments of wound management or developing Santyl outside of the US etc., etc., will come on top? And I think you've indicated single digit million dollar benefit in terms of synergies, which seems a bit low with the re-launch for Regranex and so on. So just wondering whether you're extremely conservative in terms of sales development, or what's your view?

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Adrian Hennah - Smith & Nephew Plc - CFO

Well, Julien, yes, we've guided to mid-teens sales growth as being the organic growth of the business we're acquiring. We've also signaled, in our financial model, we've only got very modest revenue synergies in our financial model, but equally, as we look to the longer term we're behind this thing for top line synergies. It's what we're after, so we see, in the longer term, significant material here.

But in terms of what we put in our financial model, we've put in the mid-teens sales growth for the entity we're buying and then, in terms of our financial model, some modest synergies. Obviously, we hope to beat them, but that's for the future.

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Julien Dormois - Exane BNP Paribas - Analyst

Okay.

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Operator

Yi-Dan Wang, Deutsche Bank.

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Yi-Dan Wang - Deutsche Bank - Analyst

I have a few questions. First of all, can you give us a sense of what the operating leverage is available from the incremental sales that you get from this business?

And then secondly, can you also give us some idea of how big the Regranex product is, and Oasis product is, within the business that you've just bought?

And then, thirdly, on Santyl, can you just clarify why you think that there won't be much competition for a while? Thank you.
Adrian Hennah - Smith & Nephew Plc - CFO
Well, in terms of the operational leverage, Yi-Dan, we do see it as substantial and we tried to illustrate why in the prepared remarks we made. Today the gross margin is -- and you'll see it, we put that in an appendix, [so you'll see what we've got], Yi-Dan -- the gross margin is pretty high, but the S&GA, the selling, general and admin, as a percentage of sales is also pretty high.

We do not expect that to increase at anything like the rate of the mid-teens sales growth. So actually, the operational leverage we see as a substantial driver of the expected return and how we reach our above cost of capital return in the third year. So the answer to that is substantial, and we've given you a fair number of pointers, I think, Yi-Dan, to build up a model for that.

In terms of Regranex and Oasis, they are after -- we said Santyl's about three-quarters, so there are a number of other products. Regranex and Oasis are the biggest two of them, but they're spread around the balance. We're not going to give any more specific guidance.

And in terms of the last one, I've forgotten what it was, but maybe you -- what was the third question, Yi-Dan, sorry?

Olivier Bohuon - Smith & Nephew Plc - CEO
Santyl, why do we believe there's no competition in Santyl?

Adrian Hennah - Smith & Nephew Plc - CFO
The regulatory blocks to Santyl having a competitor. Do you want to do that one, Roger?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Yes, as we've already talked, there are other forms of debridement, but we think Santyl offers a very simple and clinically effective solution. In terms of future competitors there, I believe then that the route of the biologic license offers some indirect protection in the sense that the regulatory pathways are extremely expensive as well as very lengthy to be able to produce a biosimilar in the US. And that's how we view future competition.

Adrian Hennah - Smith & Nephew Plc - CFO
And you get good visibility about who's tracking towards it. So we've obviously looked very, very carefully at this area.

Olivier Bohuon - Smith & Nephew Plc - CEO
Business intelligence has been pretty clear on this.

Yi-Dan Wang - Deutsche Bank - Analyst
Okay. Thank you for that. So a clarification then; on the operational leverage for that cost base that you're carrying for SG&A, shall we just expect to grow more or less in line with inflation? Or are you effectively suggesting that the resource that you have is sufficient and you just need to grow [into it]?

Adrian Hennah - Smith & Nephew Plc - CFO
Clearly, it's not going to not grow, Yi-Dan. Clearly, it's going to grow. In our modeling we've regarded a material component of our SG&A as fixed and growing in line with inflation; a material component as variable and growing at something less than sales growth. And it's not reasonable to
ask anything more precise than that, but you're on the right track for doing the calculation we've done to get ourselves comfortable on the third year beating the cost of capital.

Yi-Dan Wang - Deutsche Bank - Analyst
Okay. Thank you.

Operator
Martin Brunninger, Nomura.

Martin Brunninger - Nomura - Analyst
I have a few questions. Can you give us some indication on the sales split of these three products and how the reimbursement is split as well, how much is reimbursed and how much is self-pay?

And, given that you paid [71 times] EBITDA for this business, I think it's quite expensive. But could you give us some more indication on the synergies in more detail rather than the $20 million, where they come from, do you see synergies on the COGS? What about the manufacturing facilities, and also personnel on the SG&A side?

And I take it that you will step up on R&D, given that you just said you bought an R&D capacity; if you can just give us the run rate for OpEx for the next few years? Thank you.

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Just taking the first part of your question, I think, just to reiterate our guidance, Santyl is three-quarters of the sales, and then Regranex and Oasis form the majority of the other quarter with some small heritage products.

Adrian Hennah - Smith & Nephew Plc - CFO
And the reimbursement?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division
Yes, and in terms of the reimbursement, then I would say the majority are reimbursed in the US. There is some private pay channel, but the majority is reimbursed.

Adrian Hennah - Smith & Nephew Plc - CFO
But we see the company Healthpoint as having done a jolly good job in getting reimbursement, and that's actually what we see, and the capability to do that that they have, which is very positive.

In terms of the multiples, Martin, the way we look at it, it's 4.1 times multiple sales, if you look at 2012 sales, the last 12 months of forecast 2012 sales which, frankly, is pretty much in the middle of the range for these sort of acquisitions. The EBITDA multiples are clearly hard to look at in these sort of companies, because some companies like this have literally no revenue and they've got huge EBITDA multiples, so one sees huge ranges.
When we look at the EBITDA that we expect there to be in 2012, and look at that on a last 12-month basis, we see an EBITDA multiple of 18 if you look before the R&D cost, and around 50 if you look after the R&D cost. And, again, we see that as being quite a sensible sort of multiple.

When you then bring it down and you look in a granular fashion about where you expect to get the return from, which is, again, why we start -- it's not the only financial measure we look at, but we start on these things firmly on, is it going to earn a return to shareholders above the cost of our capital by the third year, and then what are the risks around achieving that. And, again, we've been very focused on that; we've done a lot of modeling on it and, I suspect, given you a sense in this call that we're relatively conservative in putting together the numbers, that we've looked at that.

So we're quite comfortable with that. Now, clearly within that are the synergy numbers that you described. We mentioned that we have got very few revenue synergies in that financial calculation. Again, we do expect things beyond the financial calculation; we haven't got them in the financial calculation.

We expect around $20 million of cost synergies. They are almost exclusively back room stuff. This is a fast-growing business. We do not expect reductions in sales, but obviously, over time, some degree of bringing together of sales force optimization exactly, but with our own sales forces.

But essentially, this is back room stuff, and we have an infrastructure in the United States that serves our Wound business, but also our Orthopedic business. We'd expect that sort of stuff to be integrated in a measured pace, but firmly, into our own business, and we're comfortable with $20 million there.

We're not going to go into more detail for reasons, I'm sure, you can appreciate exactly where that's coming from (multiple speakers).

Olivier Bohuon - Smith & Nephew Plc - CEO

Again, the model has not been built in thinking cost synergies. Here we are in a development; we want to accelerate the growth, and so our synergies are here and they will remain here. So I believe, however, that we have a significant, and Adrian was mentioning the competitive model which is what it is, but we definitely have synergies, sales synergies and potential expansion in other countries which are very important and not quantified there.

Adrian Hennah - Smith & Nephew Plc - CFO

And to your third question, Martin, about the step-up in R&D cost. I'm not sure we can give you any more than we gave you in the prepared remarks, and that was really just to try and distinguish -- the model of R&D this organization has is not deep research.

We're not talking about a high research-focused organization; it's much more a -- it's commonly referred to as search and development. They have a capability to get out and find interesting products, products they can do things with, and that's been their history, and a pretty successful history. We've been impressed by that capability, and roughly running along at $15 million a year of cost there.

And then, there's the funding of the pipeline on top of that. That is dominated in the short to medium term by 802, and we've given you a sense of roughly $25 million a year five years, a bit of front-end loading in that and hence, the $40 million or $50 million total R&D spend that we see in the short to medium term in this business.

I'm not sure we can give you any more than that I'm afraid, Martin.

Martin Brunninger - Nomura - Analyst

Yes, sure. No, that's fine. One thing is, just a remark, it's not such an immature business as you described. I know we have seen biotech multiple 10 years ago in that range and I do appreciate you have three products on the market. But you have already penetrated that market by 20%, given
the figures you gave us earlier of your total market size, and the margins from what you have given us seems to be in the mid-teens range already. So that’s what you see in dermatology businesses. I appreciate it’s an innovative business, but what growth rates -- the mid-teens growth rates that you’re assuming, how much of those growth rates are in the US, in the current market, and how much do you assume from cross-selling into Europe?

Adrian Hennah - Smith & Nephew Plc - CFO

Well, we’re not going to go into vast more details on this, Martin, but just suffice it to say, the mid-teens we’ve got in there is dominantly the United States. Just as the barriers to entry for regulatory give us some comfort in terms of competition in the United States, they also provide some barriers to getting into some of the markets. So we’re realistic about those.

We do expect to crack those, over time, and find ourselves another way, but dominantly in what you’re looking at now is the United States. There’s other potential over time elsewhere, but please don’t press us for any more details on that because we’re not going to go down any more.

Martin Brunninger - Nomura - Analyst

Yes, okay. Thank you very much.

Operator

Chris Gretler, Credit Suisse.

Chris Gretler - Credit Suisse - Analyst

Congratulations on what looks like another sensible deal, so I just have now two questions. First, respect to distribution, could you elaborate? I stepped out for a second, so if you have already answered, I’m sorry, but on distribution, could you basically elaborate on how the distribution model works in the US, in particular, and whether you have -- sell only through direct sales people or whether you also have an agent set up?

I was just a bit astonished to see that the sales force productivity is below $1 million for this type of business, which I thought was relatively low, but maybe if you could discuss that? That would be my first question.

The second question is, now with respect to the retention of key personnel, how you make sure in particular these sales people that they stay on and that it’s now quite a change from a smaller type company into another larger setup, so that they stay happy. I guess they were also compensated with equity in this firm, so now that is obviously changing as well, if you could discuss that topic as well, that would be helpful. Thank you.

Olivier Bohuon - Smith & Nephew Plc - CEO

Hi, Christoph, thank you for the questions. I guess in terms of solution, just to clarify before we answer, are you talking about the sales rep model that we have in the US?

Chris Gretler - Credit Suisse - Analyst

Yes, I mean the distribution model for Healthpoint in the US.
Olivier Bohuon - Smith & Nephew Plc - CEO

Okay, Roger will answer, but just we are direct there. We have [360] people now, which is what we have in the US. So Roger, do you want to go further on this one?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Yes. Olivier's right, we have a sales organization of 215 people who are focused principally on three areas; the physicians' offices, wound clinics, those are the clinics attached to acute care facilities; and then also, the long-term care sector.

The products are physically distributed through intermediaries, the med/surg and the drug wholesalers. It's concentrated around a small number and, historically, the products have been accessed through the usual group purchasing organization contracts as well. So a very typical US distribution model where the sales force are creating the end market demand, and intermediaries are providing the product.

Chris Gretler - Credit Suisse - Analyst

So there is no risk that we see a drop a sales force because of a change in distribution model as a result of your takeover in your view?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

No, we don't see that, but I would stress that we see this as a very -- I'm building on to your second question -- a very high performance sales model and sales force. I think what we've seen is strong market analytics with very clear account targeting and management, and a sales force that is extremely well run and high performing.

So we believe we want to build on those capabilities, and not do anything to disrupt the progress that they've made.

Chris Gretler - Credit Suisse - Analyst

And the sales force productivity in terms of dollars per capita, is this in line with the industry in your view?

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

We believe it's at the top end in terms of the industry. They're very, very focused, so when you -- at the moment, the sales force split is, one side of the sales force is directly focused on Santyl and carries a small number, so less than five of Regranex accounts. And then there's a dedicated sales force on Oasis, so I'm sure in your calculations, you've netted all the numbers.

When you break them down, then what you see is, as I say, just to re-stress, a very high performing sales force at the high end of productivity levels for the industry.

Chris Gretler - Credit Suisse - Analyst

Thank you. And the incentivation, sorry?

Olivier Bohuon - Smith & Nephew Plc - CEO

Well, in terms of retention of key people, obviously, this was a concern and it's always a concern when you acquire a company, but we have put plan together to secure the key staff of the company, so it's not for us anything to worry about.
Adrian Hennah - Smith & Nephew Plc - CFO

No, and there's been a lot of contact in preparation because this is a private company, so there's been a lot of face-to-face contact, and we feel pretty comfortable [in this area].

Roger Teasdale - Smith & Nephew Plc - President, Advanced Wound Management Division

Yes, I think just a final comment on that. I think we greatly appreciate the type of skills and capabilities that come with the transaction. There's some very seasoned executives, and we believe there's a lot of potential for them not only to grow this business further and to build on the model that they've set up, but also to influence our Smith & Nephew operations as well.

Chris Gretler - Credit Suisse - Analyst

Okay. Thank you.

Olivier Bohuon - Smith & Nephew Plc - CEO

Okay. Well, thanks a lot. Thank you for listening today, and we look forward to seeing many of you at the capital market event this evening. So thanks a lot, good day, and see you in New York. Bye-bye.