

July 28, 2008

Mr. Stephen Hammann Health Physicist Division of Nuclear Materials Safety U.S. Nuclear Regulatory Commission Region I 475 Allendale Road King of Prussia, PA 19406-1415

Amendment of License 06-30764-01 (Current Amendment No. 12) Docket No. 03036099

Re: Advanced Care Medical Ownership Change

Dear Mr. Hammann

Advanced Care Medical is requesting that the referenced <u>possession – storage packaging license</u> be changed as follows

 Effective August 1, 2008, the ownership of Advanced Care Medical, 115 Hurley Road, Building 3A, Oxford Ct, 06478 will transfer from Gary Lamoureux: to: Biocompatibles International 115 Hurley Road Oxford, Ct 06478

There will be no change in the company name, location, Radiation Safety Officer or organizational structure. James Matons will retain his responsibilities as President and will be the highest level executive located at 115 Hurley Road, Oxford CT.

A. Please see attached Biocompatibles press release for a complete description of the transaction.

2 C

29

NH IO:

5

- B. The Advanced Care Medical name will not change Contact: Wayne Richardson RSO 203 262 4194 X 105
- C. There are no changes in personal or duties that relate to the licensed program
- D. There are no changes in the organization, location, facilities, equipment or procedures that relate to the licensed program
- E. There will be no changes in the surveillance program (surveys, wipe test tests, quality control).

 115 Hurley Rd, Building 3A, Oxford, CT 06478 • Tel: 888-263-3090 | 203-262-4194 • Fax: 888-227-0755 | 203-262-4199

 www.advancedcaremed.com

 NMSS/RGNI MATEF.ALS-002



- F The facility will conduct business as normal with the same name. There will be no decommissioning
- G. The transferee Biocompatibles International, will abide by all constraints, Conditions, requirements and commitments of the transferor (Gary Lamoureux).
- H. The company name will remain as Advanced Care Medical. There will be no decommissioning
- 2. Amend Item F (12-5-05) referenced in the 8/11/06 letter
 - From: " <u>On occasion</u> radioactive material, which is being boxed for Shipment will be stored in this room overnight"
 - to

Radioactive material, which is being boxed for Shipment may be stored in this room overnight"

Please contact me if you have any questions about this amendment request.

Sincerely,

Wayne W. Richardson Radiation Safety Officer Advanced Care Medical 115 Hurley Road, Bldg. 3A Oxford, CT 06478 203 262 4194 X 105 wayne@wwmedtech.com Biocompatibles plc - medical technology supplier of drug device combination products - ... Page 1 of 3

Biocompatibles

Acquisition of BrachySciences

25/07/2008

Biocompatibles is pleased to announce the acquisition of the business and net assets of BrachySciences Inc. and its affiliated companies¹ together "BrachySciences") for a total consideration of up to US\$21.6 million (c.£10.9 million), of which up to US\$8.6 million (c.£4.4 million) is payable at closing and a further US\$12 million is payable based on the achievement of EBITrelated milestones over the years 2009-2011 ⁱⁱ.

BrachySciences

BrachySciences is a medical device business located in Oxford, Connecticut, principally marketing implantable "seeds" that deliver radiation for the treatment of prostate cancer, a treatment known as brachytherapy. In the year to 31 December 2007, the business generated revenue of US\$9.7 million and profit of US\$0.2 million.

Prostate cancer is the second most common cancer affecting men, behind lung cancer. The most common treatments when the disease is localised to the prostate are surgery, external beam radiation and brachytherapy (internal radiation) with the highest market penetration of brachytherapy being in the US, where Biocompatibles estimates BrachySciences' market share to be around 5%.

Transaction rationale

BrachySciences is expected to prove to be a valuable strategic investment for Biocompatibles:

 BrachySciences' products are a local treatment for a locally-dominant cancer delivered under image-guidance, which is the same concept as Biocompatibles' Drug-Eluting Bead products. BrachySciences' seeds deliver radiation; Biocompatibles' Beads deliver drugs.

A central conviction underpinning Biocompatibles' oncology strategy is that the core approaches to cancer treatment, namely systemic drug administration and surgery, can and will be supplemented by much wider use of minimally-invasive local treatments for locally-dominant disease. The rationale behind locally-delivered therapy is to achieve a better side-effect profile, lower cost and potentially improved survival. BrachySciences' products are in this category.

- BrachySciences will also act as a US base for Biocompatibles, enhancing the Company's ability to promote its products and technologies to US cancer physicians and to US companies; and thereby underpinning its growth plans in the world's most important market. Conversely, Biocompatibles will support the launch of Brachysciences' products outside the US, through its network of marketing relationships.
- BrachySciences has recently launched a promising new product, AnchorSeedTM, which is designed to provide greater assurance of the accurate delivery of radiation. The product has FDA approval and initial market evaluations have been positive. Sales are expected to build over the next twelve months.

BrachySciences is trading profitably and generating cash. Its acquisition therefore contributes to Biocompatibles' intention to move into sustainable profitability.

http://www.biocompatibles.com/news/acquisition-of-brachysciences-/

(Advanced CARE Medical

to be managed.

As commented in the report last year, we address this issue by making three specific commitments each of which can be monitored by our shareholders. First, we commit to a clear medium-term vision, described above, along with annual goals that mark the route. Second, management undertakes the discipline of providing financial guidance to investors and the rest of the financial community on the level of sales and cash consumption. Third, the Board reviews whether there are specific opportunities for accelerating the delivery of value to shareholders. This approach was taken in 2002 with the sale of the cardiovascular stent and contact lens businesses, and the subsequent return to shareholders of £123m of capital.

Acquisition and Business Development Activity

The Board monitors a short list of acquisition and in-licensing opportunities, which are typically companies that would strengthen the competitiveness of our Bead product lines and bring forward the date at which we achieve sustainable profitability. During 2007 we reviewed several of such opportunities.

Corporate Governance

The Directors place a high priority on maintaining high standards of corporate governance and rigorous management systems, and the Company is in compliance with the Combined Code on Corporate Governance. Biocompatibles' quality management system incorporates a number of relevant provisions from the Code (and the Turnbull Guidance), including those relating to risk management and internal control. The internal control risk review ensures that, as the Group and its technology evolves, its approach to risk keeps pace. The Company's continued accreditation to the ISO 9001-2000 quality standard represents independent verification of the Company's compliance with some of the key elements of corporate governance.

Since 2001, the Company has also held the Investor in People accreditation. This recognises the Group's dedication to employee development.

Memorandum and Articles of Association

Management of Risk

The Biocompatibles' share price is more volatile than the average share on the London stock market, not least because the Company is part of a volatile sector – of small/mid size healthcare technology companies; and the sector had a very weak period in the last few months of 2007, from which Biocompatibles was not, regrettably, immune. But the Directors take the view that the Company's investors are aware of this "sector risk" and that they are looking for the exceptional returns that can be achieved when healthcare technology is successfully commercialised. The Directors therefore focus their review of risk on the issues that can cause a delay to ultimate success as well as on those that can cause failure.

Outlook

Biocompatibles operates in the healthcare industry, where some important trends affect most companies. These include the cost escalation associated with the aging population - a process in which the price of expensive new therapies is an additional financial burden on payers. Evidence-based medicine and cost-benefit analysis - especially of new therapies - is also increasingly a factor.

We consider that Biocompatibles is well positioned in the context of these issues. Cancer is a disease that affects older people and one where there is self-evidently scope for more effective and

Crispin Simon, Biocompatibles' Chief Executive commented "We are delighted with this transaction. BrachySciences fits well with our business strategy and our commitment to growing revenues and establishing sustainable profitability. We look forward to working with the BrachySciences people and serving their customers.

We will continue to look for bolt-on acquisitions that support our strategy of building a profitable Drug-Device business".

Contact us

Notes to Editors

Glossary of Terms

Notes:

(i) World Wide Medical Technologies LLC and Advanced Care Medical Inc.

(ii) The share element of the initial consideration is calculated using the 24 July 2008 closing price of Biocompatibles shares of 139.75p and a €:£ exchange rate of 1.983.

About Biocompatibles

Read detailed information about the business.

Board of Directors

Read biographies of board members.

Advisors

Read biographies of principal advisors.

Biocompatibles International plc Tel: +44 (0) 1252 732732 Fax: +44 (0) 1252 732777 General email: info@biocompatibles.com Login to your account

© 2008 Biocompatibles International plc - Site Map - Terms & Conditions - Accessibility - Help

Biocompatibles

The Business

Biocompatibles is a leading medical technology company in the field of drug device combination products, operating through three businesses. The International Division conducts the marketing of Biocompatibles' approved Bead products, which are sold to hospitals by our distribution partners, including AngioDynamics Inc and Terumo Corporation. The Drug Delivery and CellMed businesses are engaged in new product development and licensing.

The Company's main programmes are Drug-Eluting Stents, licensed to Medtronic; Cosmetic dermatology Beads licenses to Merz Pharmaceuticals; Drug-Eluting Bead products for the treatment of cancer, by Endo-Vascular and Non-Vascular delivery, which is unlicensed; and Drug-Eluting Beads for the treatment of stroke, which is also unlicensed.

Our 'Business Model' is to own the most valuable products in our portfolio and pipeline; and to engage with partners where their scale and/or focus offers more effective execution.

We aspire to be the leader in the fields in which we operate and if we slip significantly behind the competition or our own plans, then we will seek to crystallise value for shareholders. We consider ourselves to be the leader in the field of Drug-Eluting Beads for the treatment of caner; and in the field of stem cell derived therapies for the brain. Our task is to develop these leading technology positions into worthwhile market positions.

The Vision

Our Vision for Biocompatibles as a whole remains the development of a high margin, high growth, financially strong, business based on a range of valuable drug device combination products.

The vision of the Biocompatibles businesses based in Farnham is also unchanged - the creation and leadership of a market for Drug-Eluting Beads and the recognition of our products as a Gold Standard treatment for Hepatocelluar Carcinoma and Metastic colo-rectal cancer.

CellMed's vision is still to be first to market with an engineered stem cell product - the Drug-Eluting CellBead for the treatment of stroke.

The Technology

Biocompatibles has a portfolio of granted patents around three biomedical polymer systems - the NFil Technology™ licensed from the Biocure affiliate of Novartis' Ciba Vision subsidiary, which is used in the Drug-Eluting Beads programme; the CellMed alginate technology, CellBeads®, which is required for the encapsulation of biological agents; and the PC Technology™ that was the Group's original platform. Beyond these core polymer systems, we have additional patents covering a variety of more product specific Drug Delivery inventions for the delivery of both chemical and biological agents; and for both medical device and pharmaceutical products.

Building Value

Biocompatibles' financial profile is being transformed by the growth in sales and gross margin; but the Group is not yet profitable and the most commonly accepted measure of business success is therefore not available to investors or other stakeholders. This imposes an obligation on the Board and management to be very specific about how the value of the Group is to be increased and risk is

Biocompatibles International plc Chapman House Famham Business Park Weydon Lane, Farnham Surrey GU9 8QL United Kingdom Tel: +44 (0) 1252 732732 Fax: +44 (0) 1252 732703 www.biocompatibles.com

- BrachySciences' Chief Executive and Founder, Gary Lamoureux, and President, Jim Matons, will remain with the business. They have substantial commercial experience in the medical device industry. They will continue to drive the BrachySciences business forward and will add to the strength and depth of Biocompatibles' management team.
- Like Cellmed, acquired by Biocompatibles in 2005, Brachysciences was established and developed by a successful entrepreneur who is remaining within the business, with a substantial element of deferred consideration and management autonomy to sustain the entrepreneurial spirit.

Gary Lamoureux, BrachySciences Chief Executive, commented "I am delighted to be working with Biocompatibles, taking BrachySciences to the next level and helping to realise the potential of Biocompatibles' existing assets."

Transaction Details

Upon closing, Biocompatibles will pay to the shareholders of BrachySciences and certain affiliated companies an initial consideration of US\$8.6 million, with up to a further US\$1.0 million payable in cash reserved against specific warranties and indemnities. The initial consideration will be satisfied by the payment of US\$5.5 million in cash and the issue of 1,132,685 Biocompatibles shares and is subject to a potential reduction due to a working capital adjustment. The share consideration is equivalent to \$3.1 million valued at the closing share price of Biocompatibles' ordinary shares on 24 July 2008. It is a condition to closing that BrachySciences' shareholders agree not to dispose of the new Biocompatibles ordinary shares that they receive as part of the consideration payable to them for a period of one year from the closing date.

There is provision for additional contingent consideration up to a total of US\$12 million. This additional consideration is payable in three milestone payments of up to US\$4 million each, with each payment comprising 35% cash and 65% equity, and is based on the achievement of individual EBIT and sales targets in each of the financial years 2009-2011.

The value of the gross assets being acquired, excluding intangible assets, was US\$2.5 million as at 31 December 2007. The directors of Biocompatibles believe that, had the acquisition taken place on 1 January 2007, it would have had the effect of modestly reducing the group's net loss for the year commencing on that date. This statement should not be interpreted as implying any forecast in respect of Biocompatibles' earnings per share for the first full year following the transaction.

The transaction is expected to close on 1 August 2008.

Trading and Guidance Update

- On 9th January 2008, the Company indicated that 2008 revenue was expected to be in the range of £12million to £15million; and that year end cash was expected to be approximately £30million.
- Group revenue and cash in the first half of 2008 were in line with expectations.
- The Company now believes that following the acquisition of BrachySciences, the group's key financial measures in 2008 will be follows:
 - With the inclusion of BrachySciences for part of a year, the expectation for 2008 revenue is increased to a new range of £15 million to £17 million.
 - Guidance for closing cash is reduced by £2 million to £28 million, due to around £4m of acquisition related expenditure, partly offset by lower than expected cash burn in Biocompatibles.

better tolerated treatments, like Drug-Eluting Beads, in comparison with the traditional cornerstones of oncology - systemic administration of toxic drugs.

Our development programmes are also far less expensive than those that are required for new pharmaceutical products. It is therefore in this context that the Directors consider our strategic positioning to be eminently achievable - seeking to prove superiority - clinically and economically.

In summary, the Board considers that the technology and know-how in both Farnham and Alzenau is developing well and that the progress with the core programmes and our commercialisation strategy has been good. Our year-on-year financial performance has improved, our cash position is strong and we have made good progress against our milestones. We continue to be highly focused on the creation of value for our shareholders.

Investment Overview

Information for investors in Biocompatibles.

Share Price

BII 162p (+ 9p) More.

Financial Reports

Download Annual & Interim Reports.

Biocompatibles International plc Tel: +44 (0) 1252 732732 Fax: +44 (0) 1252 732777 General email: info@biocompatibles.com

© 2008 Biocompatibles International plc - Site Map - Terms & Conditions - Accessibility - Help

Login to your account