

# **Neovasc Inc. Management's Discussion and Analysis**

Form 51-102F1

FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2011 AND 2010

# FORM 51-102F1: MANAGEMENT'S DISCUSSION AND ANALYSIS

This discussion and analysis covers the unaudited interim consolidated financial statements of Neovasc Inc. (the "Company" or "Neovasc") for the three and six months ended June 30, 2011 and 2010.

The management's discussion and analysis ("MD&A") of financial condition and results of operations should be read in conjunction with the unaudited interim consolidated financial statements and notes thereto for the three and six months ended June 30, 2011 (included as part of Neovasc Inc.'s quarterly filing).

#### FORWARD-LOOKING STATEMENTS

This discussion and analysis, contains forward-looking statements that are not based on historical fact, including without limitation statements containing the words "believes", "may", "plan", "will", "estimate", "continue", "anticipates", "intends", "expects", and similar expressions, including the negative of such expressions. These statements are only predictions.

Forward-looking statements and information should be considered carefully. Undue reliance should not be placed on forward-looking statements and information as there can be no assurance that the plans, intentions or expectations upon which they are based will occur. By their nature, forward-looking statements and information involve numerous assumptions, known and unknown risks and uncertainties, both general and specific, which contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements and information will not occur and may cause actual results or events to differ materially from those anticipated in such forward-looking statements and information. The assumptions made by Neovasc include the ability of the Company to obtain and enforce timely patent protection for its technologies, the development of products; the timing of receipt of regulatory approvals; the sufficiency of budgeted expenditures in carrying out planned activities; and the availability and cost of labour and services (see 'Risks and Uncertainties').

More particularly and without limitation, this discussion and analysis contains forward-looking statements and information concerning the potential of Neovasc and the timing of market acceptance of the Company's technology products.

There are also other factors that may cause the actual results, events or developments to be materially different from any future results, events or developments expressed or implied by such forward-looking statements and information. Such factors include, among others, the stage of development, additional capital requirements, the impact of the global economic downturn, the ability to develop, manufacture and commercialize its products in a cost-effective manner, the ability to integrate newly-acquired businesses and the ability to protect Neovasc's intellectual property (IP).

Neovasc disclaims any obligation to update any such factors or to publicly announce the result of any revisions to any of the forward-looking statements or information contained herein to reflect future results, events or developments, except as required by law.

All financial information is prepared in accordance with International Financial Reporting Standards ("IFRS") and is expressed in Canadian dollars.

Date: August 24, 2011

#### **OVERVIEW**

# **Description of the Business**

Neovasc Inc. is a specialty vascular device company that develops, manufactures and markets medical devices for the rapidly growing vascular and surgical marketplace. Current products include the Neovasc Reducer<sup>™</sup>, a novel product in development to treat refractory angina, and a line of advanced biological tissue technologies that are used to enhance surgical outcomes and as key components in a variety of third-party medical products, including transcatheter heart valves.

Neovasc's business operations started in March 2002, with the acquisition of Neovasc Medical Inc. ("NMI") (formerly PM Devices Inc.("PMD")),NMI manufactures a line of collagen based surgical patch products made for use in cardiac reconstruction and vascular repair procedures as well as other surgeries. The products are made from chemically treated bovine and equine pericardial tissue.

In May 2003, Neovasc acquired Angiometrx Inc. ("ANG"). ANG developed a technology called the "Metricath<sup>®</sup> System," a catheter-based device that allows clinicians to measure artery and stent size and confirm stent deployment during interventional treatment of coronary and peripheral artery disease. In 2009, Neovasc ceased all activities related to the Metricath.

In July 2008, Neovasc acquired two pre-commercial vascular device companies based in Israel: Neovasc Medical Ltd. ("Neovasc Medical") and B-Balloon Ltd. ("B-Balloon") (the "Acquisitions"). Neovasc Medical had developed and owned IP related to a novel catheter-based treatment for refractory angina, a debilitating condition resulting from inadequate blood flow to the heart muscle. Refractory angina affects millions of patients and at present there is no effective cure. B-Balloon had developed certain products intended to solve problems encountered by physicians when attempting to place vascular stents at locations where an artery branches from the aorta (the "ostium") or where an artery splits into multiple branches (a "bifurcation"). Currently Neovasc is not developing any of the B-Balloon technologies and is focusing its efforts on the Neovasc Medical treatment for refractory angina.

# **Product Portfolio**

# **Peripatch Products**

Neovasc manufactures the *PeriPatch<sup>TM</sup>* ("PeriPatch") line of advanced biological tissue products that are manufactured from pericardium, which is the protective sac that surrounds the heart of an animal. Neovasc uses its proprietary processes to convert raw pericardial tissue from animal sources into sheets of implantable tissue that can be used as a reinforcement during surgery (for example, to patch a hole in an artery or to help repair a hernia) or that can be incorporated into third party medical devices (for example, for use as the material for artificial heart valve leaflets or as a covering on a vascular stent). Peripatch tissue retains the mechanical characteristics of natural tissue and is readily incorporated into the body without rejection. Neovasc's Peripatch material was originally developed to fabricate artificial heart valves and has a 20-year history of successful implantation for heart valve and other surgical applications. Peripatch tissue can be manufactured to meet the mechanical and biological characteristics required for a wide variety of applications, such as surgical reinforcement patches or aortic heart valve leaflets.

The product line includes: the  $PeriPatch^{TM}$  Sheet, and  $PeriPatch^{TM}$  EQ Sheet, which are rectangular patches made from bovine (cow) or equine (horse) tissue, applied as internal bandages to repair weak or damaged organs or vessels. These are typically supplied sterile to customers who then use the sheets in surgical procedures.

The Company also provides a range of custom Peripatch products to industry customers for incorporation into their own products. These include Peripatch tissue fabricated from bovine, equine and porcine sources and offered in a wide variety of shapes and sizes. Neovasc works closely with these industry customers to develop and supply tissue to meet their specific needs.

This often includes providing tissue in custom shapes or molded to 3-D configurations. The Company also provides product development and specialized manufacturing services related to Peripatch tissue-based products.

# Regulatory Status

The Peripatch Sheets made from bovine tissue are cleared for sale in the United States, Canada and Mexico. Peripatch Sheets made from bovine pericardium sourced from Australia are cleared for sale in Europe. The Peripatch EQ Sheets made from equine tissue are approved for sale in the European Union and in Canada. A number of third-party products which incorporate Peripatch tissue are approved for sale or have pending approvals in various markets. There is no assurance that these approvals for third-party products will be obtained.

#### Distribution

Certain sizes of sterile Peripatch and Peripatch EQ Sheets for surgical repair, specifically "strips" which are used primarily for vascular reconstruction procedures, are distributed exclusively by LeMaitre Vascular (Boston, MA) in the United States and Europe. Non-strip sizes of Peripatch Sheets for surgical repair are distributed by LeMaitre Vascular as well as a number of other independent distributors in Europe and elsewhere. The Company's goal is to steadily increase its distribution reach in new target markets, while increasing market share in current markets and in particular in the United States.

Distribution of custom Peripatch tissue products to industry customers is handled directly by Neovasc through its business and product development group.

#### **Neovasc Reducer**

The Neovasc Reducer<sup>TM</sup> (the "Reducer") is a treatment for patients with refractory angina. Refractory angina patients have severe, debilitating chest pain due to insufficient blood supply to the heart muscle, or myocardium, which is not amenable to revascularization. Using a simple catheter-based procedure, the Reducer is implanted in the coronary sinus, the major blood vessel that sends de-oxygenated blood from the heart back to the systemic circulation. The Reducer has been clinically demonstrated to provide significant relief of chest pain in refractory angina patients. There are approximately 1,000,000 new patients each year in the United States and Europe with recurrent angina who are potential candidates for the Reducer, either because they cannot be vascularized or because they are otherwise poorly managed using conventional medical therapies. These patients represent an annual market opportunity of over \$3 billion for the Reducer product. The initial target market for the Reducer product is patients presenting with refractory angina with no other available treatment options. Once physicians have adopted Reducer for use in these refractory patients, it is expected that there will be a natural spillover into the broader recurrent angina market, which represents a substantially larger patient population.

The Reducer is an hourglass-shaped, balloon-expandable, stainless steel "stent-like" device, which is implanted in the coronary sinus, creating a restriction in venous outflow from the myocardium. It is implanted using conventional percutaneous techniques. The Reducer is provided sterile and pre-loaded on a balloon catheter system. The system is 9F sheath compatible and operates over a .035" guidewire. The implantation procedure is quick and requires minimal training. Once guidewire access to the coronary sinus is achieved, implantation typically takes less than 10 minutes.

Following implantation, the bare metal Reducer is incorporated into the endothelial tissue and creates a permanent (but reversible) narrowing in the coronary sinus. The coronary sinus is narrowed from a typical diameter of 10-12mm to approximately 3mm at the site of implantation. This narrowing slightly elevates the venous outflow pressure that restores a more normal ratio of epicardial/endocardial blood flow between the outer and inner layers of the ischemic areas of the heart muscle. This results in improved perfusion of the endocardium, which helps relieve ischemia. The physiological mechanism behind this effect is well documented in medical literature.

The clinical utility of this approach is demonstrated by a number of analogous approaches used in the past that achieved excellent clinical outcomes for angina patients by constricting or intermittently blocking the coronary sinus to improve perfusion to the heart muscle. However, these therapies required the use of highly invasive surgery or leaving a catheter in the heart for a prolonged period, making them impractical or clinically unacceptable for use in modern medical practice. Reducer was developed to deliver this therapy in a safe, simple and effective manner via a catheter that is consistent with modern medical practice.

The Reducer has demonstrated excellent results in multiple animal studies and in a clinical trial of 15 patients suffering from chronic refractory angina who were followed for three years after implantation. The six-month results from this clinical trial were published in the *Journal of the American College of Cardiology* and three-year data was presented at the ACC annual scientific meeting in March 2010. In this clinical trial, implantation of the Reducer resulted in significant clinical improvements in stress test and perfusion measurements, as well as an overall quality of life improvement in the majority of the patients.

# Regulatory Status

The Reducer is not yet approved for sale. Neovasc has completed development of the commercial-generation Reducer and the product has been transferred to pilot manufacture. The Company is presently conducting a clinical trial named "COSIRA" (Coronary Sinus Reducer for Treatment of Refractory Angina) which will provide data to support CE mark of the product. CE mark will enable the Company to begin marketing Reducer for use in Europe. COSIRA is a double-blinded, randomized, sham controlled, multicentre trial of approximately 124 patients with an expected eight to ten investigation sites. Enrollment of patients at the first center began in September 2010. Enrollment is expected to be complete in the fourth quarter of 2011 with the required six-month follow-up completed on all patients in the first half of 2012. There is no assurance that the CE mark will be granted in the time frame anticipated by management, or granted at any time in the future. Neovasc is presently developing a US regulatory approval strategy that will address the requirement for a larger randomized clinical trial that is mandatory in the US. US approval is expected in about four to five years. There is no assurance that US regulatory approval will be granted in the time frame anticipated by management, or granted at any time in the future.

# **Neovasc Tiara**

In Q2 2011 the company initiated a new project to develop a Tiara, a product for treating mitral valve disease. The Tiara product is in preclinical development to provide a minimally invasive treatment transcatheter device for the millions of patients who experience mitral regurgitation as a result of mitral heart valve disease. Mitral regurgitation is often severe and can lead to heart failure and death. Currently, conventional surgical treatments are only appropriate for about 20% of these patients since the majority are too old or frail to undergo conventional valve replacement procedures. There are approximately four million patients suffering with significant mitral regurgitation in the US. The Tiara project is an early stage, preclinical project and prototype devices are currently undergoing evaluation in animal and bench models.

# Additional Products and Third Party Sales

Neovasc provides consulting and original equipment manufacturing services to other medical device companies when these services fall within the scope of its expertise and capabilities. These activities are substantially focused on providing specialized development and manufacturing services for industry customers who incorporate the Company's Peripatch tissue materials into their vascular device products such as heart valves. The goal of these activities is to drive near-term revenues as well as support development of a long-term revenue stream through the ongoing provision of tissue and manufacturing services to customers with commercially successful device products that incorporate Neovasc tissue. Revenue earned from various contract agreements varies throughout the year depending on customer needs.

# **Regulatory Affairs and Clinical Trials**

The Company is presently in the process of obtaining the clinical trial data required to support European regulatory approval for the Reducer product. The COSIRA trial which commenced in September 2010 is expected to support this and other regulatory applications.

# **Product Development**

Product development at the Company is presently focused on completing the development and commercialization of the Reducer product as well as early stage development work on the Tiara product. The Company is also undertaking a substantial volume of product development work under contract for third parties. These third party projects are typically focused on supporting the development of products that incorporate Neovasc's PeriPatch tissue. These activities generate both near-term revenues from consulting activities for Neovasc and also are expected to drive longer-term growth as a result of the revenues that will result from future sales of new PeriPatch tissue products as well as the related manufacturing services the Company will provide for these customers once their products reach the market. The Company is also investigating potential new internal projects which leverage the Company's existing technologies, infrastructure and expertise. These new internal projects are at the proof-of-concept stage.

# TRENDS, RISKS AND UNCERTAINTIES

The Company has incurred operating losses of \$1,015,785 and \$1,989,239 for the three and six months ended June 30, 2011 (2010: \$933,734 and \$1,405,970) and has a deficit of \$68,984,476 at June 30, 2011 compared to a deficit of 66,995,237 as at December 31, 2010. The Company's ability to continue as a going concern is dependent on the profitable commercialization of its products or obtaining additional debt or equity financing to fund ongoing operations until profitability is achieved. The current economic crisis which has significantly tightened the credit and equity markets may result in required funds not being available to the Company at the time required or on terms acceptable to the Company and may also reduce demand for the Company's products.

Neovasc has a limited operating history which makes it difficult to predict how its business will develop or of its future operating results. The Company has a history of fiscal losses since its inception and will need to generate significantly greater revenues than it has to date to achieve and maintain profitability. There is no certainty of future profitability, and results of operations in future periods cannot be predicted based on results of operations in past periods. Generally, the securities of the Company should be considered a highly speculative investment.

Neovasc is subject to risks and uncertainties associated with operating in the life sciences industry and as a company engaged in significant development, regulatory, production and commercialization activity. Neovasc cannot anticipate or prevent all of the potential risks to its success, nor predict the impact of any such risk. To the extent possible, management implements strategies aimed at reducing or mitigating risks and uncertainties associated with its business.

Operating risks include but are not limited to: market acceptance of the Company's technology and products; the Company's ability to obtain and enforce timely patent protection of its technology and products; the Company's ability to develop, manufacture and commercialize its products cost-effectively and according to the regulatory standards of numerous governments; the competitive environment and impact of technological change and/or product obsolescence; the continued availability of capital to finance the Company's activities; the Company's ability to conduct and complete successful clinical trials; the Company's ability to garner regulatory approvals for its products in a timely fashion; the Company's ability to attract and retain key personnel, effectively manage growth, and smoothly integrate newly acquired businesses or technologies; limitations on third-party reimbursement; instances of product or third-party liability; dependence on a single supplier for some products; animal disease or other factors affecting the quality and availability of raw materials; conflicts of interest among the Company's Directors, Officers, promoters and members of management; fluctuations in the values of relative foreign

currencies; volatility of the Company's share price; fluctuations in quarterly financial results; unanticipated expenses; changes in business strategy; impact of any negative publicity; general political and economic conditions; and Acts of God and other unforeseeable events, natural or human-caused.

#### **FOREIGN OPERATIONS**

The majority of the Company's revenues are derived from product sales in the United States and Europe, primarily denominated in United States dollars and Euros, while the majority of the Company's costs are denominated in Canadian dollars. The Company expects that foreign currency denominated international sales will continue to account for a significant portion of its revenues. Consequently, a decrease in the value of a relevant foreign currency in relation to the Canadian dollar will have an adverse effect on the Company's results of operations, with lower than expected revenue amounts and gross margins being reported in the Company's Canadian dollar financial statements. In addition, any decrease in the value of the United States dollar or Euro occurring in between the time a sale is consummated and the time payment is received by Neovasc will lead to a foreign exchange loss being recognized on the foreign-currency denominated trade account receivable. The fluctuation of foreign exchange may impose an adverse effect on the Company's results of operations and cash flows in the future. Additionally, Neovasc may be materially and adversely affected by increases in duty rates, exchange or price controls, repatriation restrictions, or other restrictions on foreign currencies. The Company's international operations are subject to certain other risks common to international operations, including, without limitation: government regulations; import restrictions and, in certain jurisdictions, reduced protection for the Company's intellectual property rights.

Foreign currency translation gains and losses arising from normal business operations are credited to or charged to operations in the period incurred. To date, Neovasc has not entered into any foreign exchange forward contracts.

# SELECTED QUARTER FINANCIAL INFORMATION

The Company has adopted International Financial Reporting Standards ('IFRS') from January 1, 2011. The unaudited interim consolidated financial statements for the three and six months ended June 30, 2011 are Neovasc's financial statements prepared under IFRS. The section "FIRST-TIME ADOPTION OF IFRS" includes the significant accounting policies that the Company adopted under IFRS and a reconciliation of the January 1, 2010 Canadian GAAP statement of financial position to IFRS. The comparative data has been retroactively changed in accordance with the transition rules.

The following discussion should be read in conjunction with the unaudited interim consolidated financial statements for the three and six months ended June 30, 2011 and 2010.

#### DISCUSSION OF OPERATIONS AND FINANCIAL CONDITION

Results for the three and six months ended June 30, 2011 and 2010 follow:

#### Loss

The loss for the three and six months ended June 30, 2011 was \$1,015,785 and \$1,989,239, or \$0.02 and \$0.05 basic and diluted loss per share, respectively, as compared with a loss of \$933,734 and \$1,405,970 or \$0.03 and \$0.04 basic and diluted loss per share, respectively, for the comparable periods in 2010. The increase in the loss incurred in the first six months of 2011 as compared to the same period in 2010 can be substantially explained by an increase in product development and clinical trial activities of \$251,776 and an increase in non-cash share-based payments of \$491,169. In 2010 and 2011 the officers and directors of Neovasc were awarded a fixed number of options under the Company's established remuneration and incentive plans. While the actual number of options granted in each year was equivalent, under the Black Scholes model used to value the options, the significantly higher price of the Company's shares in 2011

produced a higher overall valuation of the options issued and resulted in a higher charge to the income statement in 2011.

#### Revenues

For the quarter ended June 30, 2011 revenues were \$879,405, compared to revenues of \$959,920 for the same period in 2010, a decrease of 8%. For the six months ended June 30, 2011, revenues were \$2,049,325, compared to revenues of \$2,025,761 for the same period in 2010, an increase of 1%.

Product sales for the three months ended June 30, 2011 were \$178,412, compared to product sales of \$576,884 in the same period of 2010, representing a decrease of 69%. Product sales for the six months ended June 30, 2011 were \$729,093, compared to product sales of \$952,795 in the same period of 2010, representing a decrease of 23%. The decrease in product sales in the second quarter of 2011 partly reflects a temporary suspension in sales of Neovasc's tissue products to one customer as a result of a change in product specifications that required review and approval internally and from the appropriate regulatory authorities. The requisite approvals have now been received and sales have resumed to that customer.

Contract manufacturing revenues were \$234,960 in the second quarter of 2011, compared to \$71,415 in the comparable period in 2010, an increase of 229%. Contract manufacturing revenues were \$525,211 in the six months ended June 30, 2011, compared to \$431,902 for the in the comparable period of 2010, an increase of 22%. The Company has seen an increase in contract manufacturing revenues as the Company has attracted more customers and seen larger orders from existing customers as they advance in the product development programs.

Revenues from consulting services for the three months ended June 30, 2011 were \$466,033, compared to consulting service revenues of \$311,621 in the same period in 2010, representing an increase of 50%. Revenues from consulting services for the six months ended June 30, 2011 were \$795,021, compared to consulting service revenues of \$641,064 in the same period in 2010, representing an increase of 24%. Neovasc's consulting service revenues are contract-driven and they can fluctuate from quarter to quarter as current projects are completed and new projects start.

#### Cost of Goods Sold

The cost of goods sold for the three and six months ended June 30, 2011 were \$410,957 and \$1,076,733 respectively, as compared to \$617,040 and \$1,204,399 in the comparable periods in 2010. The overall gross margin was 53% for the second quarter and 47% for the six months ended June 30, 2011, compared to 36% and 41% gross margins, respectively, in the comparable periods in 2010.

The improvement in gross margins in the 2011 periods compared to the comparable periods in 2010 can be substantially explained by a shift in product mix to higher margin product lines. Neovasc continues exploring a number of initiatives aimed at strengthening margins going forward, including implementing further manufacturing efficiencies, reviewing pricing strategies for certain products and focusing on further expanding sales of higher margin product lines such as custom tissue for transcatheter heart valves and related manufacturing services.

#### **Expenses**

Total expenses for the three and six months ended June 30, 2011 were \$1,480,163 and \$2,924,003, respectively, as compared to \$1,303,051 and \$2,212,416 in the same periods in 2010, representing an increase of 14% and 32%, respectively. Of these expenses, 46% of the increase in the second quarter and 69% of the increase in the first half of 2011 can be explained by an increase in non-cash share-based payments, as discussed in the "Loss" section above. Net of these non-cash share-based payments, total expenses increased \$100,972 and \$227,067 between the comparable periods in 2010 and 2011, substantially due to an increase in clinical trial and product development expenses for Neovasc's two product development programs.

Selling expenses were \$49,842 and \$97,088 for the three and six months ended June 30, 2011, compared to \$49,358 and \$94,249 in the comparable periods in 2011. The Company is continuing to maintain relatively constant and modest marketing costs while it focuses on growing its business-to-business revenue streams.

General and administrative expenses were \$624,262 and \$1,562,992 for the three and six months ended June 30, 2011, as compared to \$715,013 and \$1,221,306 in the comparable periods of 2010, representing a decrease of 13% in the second quarter and an increase of 28% in the first six months of 2011. The increase in general and administrative expenses in the sixmonths ended June 30, 2011 was principally due to an increase in non-cash share-based payments, as discussed in the "Loss" section above and other expenses have remained equivalent year over year.

Research and development costs, including product development and clinical trial expenses were \$806,059 and \$1,263,923 for the three and six months ended June 30, 2011, representing an increase of 50% and 41%, respectively, compared to the same periods of 2010. The increase in year-over-year research and development costs is principally due to increased investment in Neovasc's two major new product initiatives--the COSIRA clinical trial for the Neovasc Reducer and the Neovasc Tiara mitral valve development program.

# **Quarterly Information**

The following is a summary of selected unaudited financial information for the eight fiscal quarters to June 30, 2011:

# Summary of selected unaudited financial information for the eight fiscal quarters to June 30, 2011

				Quarter End	ded - l	Jnaudited		
		June 30,		March 31,	De	cember 31,	Se	ptember 30,
		2011		2011		2010		2010
		(IFRS)		(IFRS)		(IFRS)		(IFRS)
REVENUE								
Products sales	\$	178,412	\$	550,681	\$	657,417	\$	539,478
Contract manufacturing	•	234,960	•	290,251	,	318,834	,	99,878
Consulting services		466,033		328,988		342,313		375,144
•		879,405		1,169,920		1,318,564		1,014,500
COST OF GOODS SOLD		410,957		665,776		860,053		568,536
GROSS PROFIT		468,448		504,144		458,511		445,964
FYDENCES								
EXPENSES Selling		49,842		47,246		55,731		40,763
General and administration		624,262		938,730		543,700		482,775
Product development and clinical trials		806,059		457,864		614,889		330,393
Froduct development and clinical thats		1,480,163		1,443,840		1,214,320		853,931
Operating Loss		(1,011,715)		(939,696)		(755,809)		(407,967)
Operating 2000	_	(1,011,710)		(333,030)		(100,000)		(401,301)
OTHER INCOME (EXPENSE)		(4,070)		(33,758)		(61,279)		1,023
LOSS AND COMPREHENSIVE LOSS FOR THE PERIOD	\$	(1,015,785)	\$	(973,454)	\$	(817,088)	\$	(406,944)
LOSS PER SHARE Basic and diluted loss per share	\$	(0.02)	\$	(0.02)	\$	(0.02)	\$	(0.01)
				Quarter End			_	
		June 30, 2010		March 31, 2010	De	cember 31, 2009	Sep	tember 30, 2009
-		(IFRS)		(IFRS)		(GAAP)		(GAAP)
DEVENUE				, ,				, ,
REVENUE	Φ.	F7F 220	<b>ው</b>	077 470		005 400	¢.	400.070
Products sales Contract manufacturing	\$	575,320 71,415	\$	377,476 360,486		665,100 54,456	\$	436,272
Consulting services		313,185		327,879		324,316		137,505 426,590
Consulting services		959,920		1,065,841		1,043,872		1,000,367
COST OF GOODS SOLD		617,040		587,359		518,223		471,871
GROSS PROFIT		342,880		478,482		525,649		528,496
		,		,		0=0,0.10		0=0,100
EXPENSES								
Selling		49,358		44,891		105,343		94,412
General and administration		715,013		506,293		524,485		593,112
Product development and clinical trials		538,680		358,181		432,950		606,259
		1,303,051		909,365		1,062,778		1,293,783
0		1,303,031		000,000		1,002,770		,,
Operating loss		(960,171)		(430,883)		(537,129)		(765,287)
OTHER INCOME (EXPENSES)		, ,				, ,		

Product sales have been cyclical in nature from quarter to quarter. The second quarter of 2011 saw a significant decrease in activity and purchasing over the summer months while the fourth quarter of 2010 recorded our highest revenues on record. The slightly unpredictable nature of revenues is expected as third party development projects are difficult to predict and may start or stop suddenly depending on the needs of the client.

Selling expenses have remained relatively consistent from 2010 as efforts have been focused on servicing our existing customers. General and administrative expense reached a peak in the first quarter of 2011 mainly due to stock-based compensation expense of \$370,562 for options granted and vested immediately in the quarter. Product development and clinical trial costs also

peaked in the first quarter of 2011 due to the COSIRA clinical trial and some early internal development projects.

# DISCUSSION OF LIQUIDITY AND CAPITAL RESOURCES

The Company finances its operations and capital expenditures with cash generated from operations, lines of credit, long-term debt and equity financings. At June 30, 2011, the Company had cash and cash equivalents of \$435,766, as compared to cash and cash equivalents of \$1,489,027 at December 31, 2010. In addition, at June 30, 2011 the Company had restricted cash and cash equivalents related to a security on long-term debt of US\$40,000 (December 31, 2010: CAD\$50,000 held as a guaranteed investment certificate) included in long-term assets and a bank overdraft facility of \$48,649 (December 31, 2010: \$213,280) included in current liabilities.

At June 30, 2011 the Company had working capital of \$647,960 as compared to working capital of \$1,752,712 at December 31, 2010. The decrease in working capital during the first six months of 2011 was predominantly due to the net impact of a decrease in cash used to fund operations during the period; a decrease in accounts receivable, due to lower sales in the second quarter of 2011 as compared to the fourth quarter of 2010 and better than expected collections from customers during the period; an increase in inventory, as levels of tissue work-in-progress increased as new specification products were manufactured but not yet sold and an increase in accounts payable and accrued liabilities as payment on certain liabilities were deferred until the Company's recent financing was completed.

Cash used in operating activities was \$656,339 and \$931,257 for the three and six months ended June 30, 2011, as compared to \$736,831 and \$1,563,307 for the same periods in 2010. The decrease in the cash used during these periods is principally due to the reduction in working capital requirements between the periods. During the three and six months ended June 30, 2010, working capital items absorbed cash of \$28,802 and \$532,397, respectively, while in the same periods of 2011 working capital items generated \$69,921 and \$215,590, respectively.

Net cash invested in capital assets was \$19,514 and \$107,406 for the three and six months ended June 30, 2011, compared to net cash derived from investing activities of \$3,287 for the three months ended June 30, 2010 and net cash used in investing activities of \$27,568 for the six months ended June 30, 2010. During the three and six month periods in 2011 the Company invested capital to expand its clean room and manufacturing facilities.

Net cash used by financing activities was \$140,878 and \$14,598 for the three and six months ended June 30, 2011, compared to cash provided of \$1,379,913 and \$2,903,342 in the same periods of 2010. During the three and six months ended June 30, 2011, the Company used cash to reduce its bank overdraft. On February 19, 2010, the Company completed a non-brokered private placement of 5,691,658 units at the price of \$0.27 per unit for aggregate gross proceeds of \$1,536,748. Each unit consists of one common share of Neovasc stock and one-half of one common share purchase warrant of Neovasc stock. Each whole warrant entitled the holder thereof to purchase one common share of Neovasc stock at the exercise price of \$0.40 per share for a period of one-year after the closing date of the offering. Share issue costs were \$22,015. On April 23, 2010, there were 4,635,114 warrants exercised, as part of the Company's April 2009 financing. Proceeds from the exercise of the 4,635,114 warrants amounted to \$1,390,534. The remaining warrants issued as part of the Company's April 2009 financing expired on April 23, 2010. On January 17, 2011 and February 15, 2011, the Company issued 197,922 and 128,371 common shares, respectively, upon the exercise of warrants issued as part of the Company's February 2010 financing. Proceeds from the exercise of the 326,293 warrants amounted to \$130,517.

#### SUBSEQUENT EVENTS

On August 16, 2011, the Company completed a non-brokered private placement of 4,720,500 equity units at the price of \$1.00 per unit for aggregate gross proceeds of approximately

\$4,720,500. Each unit consists of one common share of Neovasc stock and one-half of one common share purchase warrant of Neovasc stock. Each whole warrant entitles the holder thereof to purchase one common share of Neovasc stock at the exercise price of \$1.25 per share for a period of two years after the closing date of the offering.

In addition, subsequent to the closing of the financing and on the same date, the Company granted 913,750 options from the Company's existing 20% fixed option pool, with an exercise price of \$1 per share, to a consultant to provide strategic advisory services over the next four years. The options vested 25% on the date of grant and will vest 25% on each of the next three anniversaries of the date of the grant, and will expire five years from the date of grant.

#### **OUTSTANDING SHARE DATA**

As at June 30, 2011, the Company had 40,771,852 common voting shares issued and outstanding. Further, the following securities are convertible into common shares of the Company: 5,605,427 stock options with a weighted average price of \$0.59. The fully diluted share capital of the Company at June 30, 2011 is 46,377,279.

# **OFF BALANCE SHEET ARRANGEMENTS**

The Company has no off balance sheet arrangements.

#### RELATED PARTY TRANSACTIONS

There were no transactions with related parties, other than those compensation based payments disclosed in Note 17 of the financial statements, during the six months ended March 31, 2011 and 2010.

# PROPOSED TRANSACTIONS

The Company is not party to any transaction requiring additional disclosure.

#### CONTROLS AND PROCEDURES

The Chief Executive Officer (CEO) and Chief Financial Officer (CFO), in cooperation with the other members of senior management and Directors, are responsible for the Company's disclosure policy. The effectiveness of the Company's internal disclosure controls have been evaluated by the CEO and the CFO, and they have concluded that the Company's control procedure provides reasonable assurance that (i) information required to be disclosed by the Company in its annual and interim reports or other reports filed or submitted by it under applicable securities legislation is recorded, processed, summarized and reported within the prescribed time periods, and (ii) material information regarding the Company is accumulated and communicated to the Company's management, including its CEO and CFO, in a timely manner.

The CEO and CFO are responsible for the design of internal controls over financial reporting in order to provide reasonable assurance that the Company's financial reporting is reliable and that financial statements prepared for external purposes are prepared in accordance with Canadian GAAP and for the safeguarding of Company assets. The CEO and CFO are aware that internal controls relating to the accounting function could be strengthened by adhering to a strict policy of segregating the duties of accounting staff to reduce the risk of unauthorized journal entries being made or a misappropriation of cash. At the Company's current size, adoption of such a policy is impractical. To reduce these risks, the CFO reviews bank reconciliation statements and performs periodic reviews of non-standard entries after they have been recorded; all cheque payments require two signing authorities. The CEO periodically reviews recorded financial information. The CEO and CFO believe that these reviews are an adequate compensating control; accordingly, there are no plans to remediate this internal control weakness. No material changes were made

to the Company's system of internal controls relating to financial reporting during the three and six months ended June 30, 2011.

#### FIRST-TIME ADOPTION OF IFRS

These are the Company's first consolidated financial statements prepared under IFRS. The date of transition to IFRS is January 1, 2010.

The accounting policies set out in the unaudited interim consolidated financial statements for the three and six months ended June 30, 2011 and 2010 note 3 have been applied in preparing the interim consolidated financial statements for the three and six months ended June 30, 2011, the comparative information presented in these interim consolidated financial statements for the three and six months ended June 30, 2010 and in the preparation of an opening IFRS consolidated statement of financial position at the date of transition.

In preparing its opening IFRS consolidated statement of financial position, the Company has applied IFRS 1 First-time Adoption of International Financial Reporting Standards (as revised in 2008). The Company has adjusted amounts reported previously in financial statements prepared in accordance with Canadian General Accepted Accounting Policies ("Canadian GAAP"). An explanation of how the transition from Canadian GAAP to IFRS has affected the Company's financial position, financial performance and cash flows is set out in the following tables and the notes that accompany the tables.

# First-time adoption exemption applied

Upon transition, IFRS 1 permits certain exemptions from full retrospective application. The Company has applied the mandatory exceptions and certain optional exemptions. The optional exemptions adopted by the Company include:

The Company has elected not to apply IFRS 3 retrospectively to business combinations that occurred before January 1, 2010.

The Company has elected not to apply IFRS 2 to awards that vested prior to January 1, 2010.

# **Reconciliation of Equity**

Previous   Effect of Canadian   transition to GAAP   IFRS   Canadian   transition to GAAP   IF		Notes	J	lanuary 1, 201	0			June 30, 2010		December 31, 2010				
Current assets         Cash and cash equivalents       (ii)       \$ 111,368       186,897       \$ 298,265       \$ 1,412,271       198,461       \$ 1,610,732       \$ 1,275,747       213,280       \$ 1,489,027         Accounts receivable       442,540       -       442,540       404,507       -       404,507       661,999       -       661,999         Inventory       404,309       -       404,309       590,787       -       590,787       469,744       -       469,744         Prepaid expenses and other assets       15,771       -       15,771       52,265       -       52,265       33,729       -       33,729		-	Canadian	transition to	)	IFRS	Canadian	transition to	_	Canadian	transition to	-		
Cash and cash equivalents       (ii)       \$ 111,368       186,897       \$ 298,265       \$ 1,412,271       198,461       \$ 1,610,732       \$ 1,275,747       213,280       \$ 1,489,027         Accounts receivable       442,540       -       442,540       404,507       -       404,507       661,999       -       661,999         Inventory       404,309       -       404,309       590,787       -       590,787       469,744       -       469,744         Prepaid expenses and other assets       15,771       -       15,771       52,265       -       52,265       33,729       -       33,729	ASSETS	•												
Accounts receivable       442,540       -       442,540       404,507       -       404,507       661,999       -       661,999         Inventory       404,309       -       404,309       590,787       -       590,787       469,744       -       469,744         Prepaid expenses and other assets       15,771       -       15,771       52,265       -       52,265       33,729       -       33,729	Current assets													
Inventory 404,309 - <b>404,309</b> 590,787 - <b>590,787</b> 469,744 - <b>469,744</b> Prepaid expenses and other assets 15,771 - <b>15,771</b> 52,265 - <b>52,265</b> 33,729 - <b>33,729</b>	Cash and cash equivalents	(ii)	\$ 111,368	186,897	\$	298,265	\$ 1,412,271	198,461	\$ 1,610,732	\$ 1,275,747	213,280	\$ 1,489,027		
Prepaid expenses and other         assets       15,771       -       15,771       52,265       -       52,265       33,729       -       33,729	Accounts receivable		442,540	-		442,540	404,507	-	404,507	661,999	-	661,999		
assets 15,771 - <b>15,771</b> 52,265 - <b>52,265</b> 33,729 - <b>33,729</b>	Inventory		404,309	-		404,309	590,787	-	590,787	469,744	-	469,744		
	Prepaid expenses and other					•			,			,		
	assets		15,771	-		15,771	52,265	-	52,265	33,729	-	33,729		
Total current assets 973,988 186,897 1,160,885 2,459,830 198,461 2,658,291 2,441,219 213,280 2,654,499	Total current assets		973,988	186,897		1,160,885	2,459,830	198,461	2,658,291	2,441,219	213,280	2,654,499		
Non-current assets	Non-current assets													
Property, plant and equipment 1,249,326 - <b>1,249,326</b> - <b>1,208,830</b> - <b>1,208,830</b> 1,224,481 - <b>1,224,481</b>	Property, plant and equipment		1,249,326	-		1,249,326	1,208,830	-	1,208,830	1,224,481	-	1,224,481		
Restricted cash equivalents 50,000 - <b>50,000</b> - <b>50,000</b> - <b>50,000</b> - <b>50,000</b> - <b>50,000</b>	Restricted cash equivalents		50,000	-		50,000	50,000	-		50,000	-			
Total non-current assets 1,299,326 - 1,299,326 1,258,830 - 1,258,830 1,274,481 - 1,274,481	•	-	1,299,326	-		_	1,258,830	-		1,274,481	-			
Total Assets \$ 2,273,314 186,897 \$ 2,460,211 \$ 3,718,660 198,461 \$ 3,917,121 \$ 3,715,700 213,280 \$ 3,928,980	Total Assets	<u>-</u>	\$ 2,273,314	186,897	\$	2,460,211	\$ 3,718,660	198,461	\$ 3,917,121	\$ 3,715,700	213,280			

# **Reconciliation of Equity (Continued)**

	Notes	Ja			June 30, 2010	)		December 31, 2010					
		Previous Canadian GAAP	Effect of transition to IFRS		IFRS	Previo		Effect of transition to IFRS	1	IFRS	Previous Canadian GAAP	transition to	IFRS
LIABILITIES AND EQUITY Liabilities Current liabilities													
Bank overdraft	(ii)	\$ -	186,897	\$	186,897	\$	-	198,461	\$	198,461	\$ -	213,280	\$ 213,280
Accounts payable and accrued liabilities Current portion of		962,512	-		962,512	615,0	54	-		615,054	647,877	-	647,877
long-term debt		39,978	-		39,978	40,3	59	-		40,359	40,630	-	40,630
Total current liabilities		1,002,490	186,897		1,189,387	655,4	13	198,461		853,874	688,507	213,280	901,787
Non-current liabilities Long-term debt		357,097	-		357,097	337,4	75	_		337,475	318,872	-	318,872
Total non-current liabilities		357,097	-		357,097	337,4		-		337,475	318,872	-	318,872
Total liabilities		1,359,587	186,897		1,546,484	992,8		198,461		1,191,349	1,007,379	213,280	1,220,659
Equity													
Share capital		60,648,625	-	6	0,648,625	63,590,5	10	-		63,590,510	64,841,468	-	64,841,468
Contributed surplus	(iii)	4,631,349	(1,012)		4,630,337	4,909,5	27	(3,060)		4,906,467	4,863,985	(1,895)	4,862,090
Deficit	(iii)	(64,366,247)	1,012	(6	4,365,235)	(65,774,2	65)	3,060	(	(65,771,205)	(66,997,132)	1,895	(66,995,237)
Total equity		913,727	-		913,727	2,725,7	72	-		2,725,772	2,708,321	-	2,708,321
Total liabilities and equity		\$ 2,273,314	186,897	\$	2,460,211	\$ 3,718,6	60	198,461	\$	3,917,121	\$ 3,715,700	213,280	\$ 3,928,980

# **Reconciliation of Equity (Continued)**

The Company has adjusted amounts reported previously in financial statements prepared in accordance with Canadian General Accepted Accounting Policies ("Canadian GAAP"). The balance sheet as at June 30, 2011 has only been reported under IFRS as Canadian GAAP does not exist for that reporting period. There are no material differences between the balance sheet as at June 30, 2011 as reported under IFRS and the balance sheet that would have been reported under Canadian GAAP applicable to fiscal 2010 if Canadian GAAP had continued to exist and been applied to the first interim reporting period of fiscal 2011.

# Reconciliation of Comprehensive Income for the Three Months Ended June 30, 2010

	Notes	Previous Canadian GAAP	1	Effect of transition to	IFRS
REVENUE					
Product sales		\$ 646,735		(71,415)	\$ 575,320
Contract manufacturing		-		71,415	71,415
Consulting services		 313,185		-	313,185
		959,920		-	959,920
COST OF GOODS SOLD	(v)	612,626		4,414	617,040
GROSS PROFIT		 347,294		(4,414)	342,880
Selling expenses		49,358		_	49,358
General and administrative expenses	(iii & v)	697,125		17,888	715,013
Product development and clinical trials expenses	(w	533,448		5,232	538,680
Amortization	(v)	30,689		(30,689)	330,000
, and a Lation	(*)	 1,310,620		(7,569)	1,303,051
OPERATING LOSS		(963,326)		3,155	(960,171)
OTHER INCOME (EXPENSES)					
Interest income		115		_	115
Interest on long-term debt		(2,991)		_	(2,991)
Loss on foreign exchange		29,313		_	29,313
		 26,437		-	26,437
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		\$ (936,889)	\$	3,155	\$ (933,734)
LOSS PER SHARE					
Basic and diluted loss per share	(vi)	\$ (0.03)	\$	0.00	\$ (0.03)

# Reconciliation of Comprehensive Income for the Six Months Ended June 30, 2010

	Notes	Previous Canadian GAAP	tı	Effect of ransition to IFRS	IFRS
REVENUE					
Product sales		\$ 1,384,697		(431,092)	\$ 953,605
Contract manufacturing		-		431,092	431,092
Consulting services		 641,064		-	641,064
		2,025,761		-	2,025,761
COST OF GOODS SOLD	(v)	1,195,571		8,828	1,204,399
GROSS PROFIT		 830,190		(8,828)	821,362
Selling expenses		94,249		_	94,249
General and administrative expenses	(iii & v)	1,184,328		36,978	1,221,306
Product development and clinical trials expenses	(v)	886,563		10,298	896,861
Amortization	(v) (v)	58,152		(58,152)	-
/ unortization	(*)	 2,223,292		(10,876)	2,212,416
OPERATING LOSS		(1,393,102)		2,048	(1,391,054)
OTHER INCOME (EXPENSES)					
Interest income		229		-	229
Interest on long-term debt		(5,329)		-	(5,329)
Loss on foreign exchange		(9,816)		-	(9,816)
		 (14,916)		-	(14,916)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		\$ (1,408,018)	\$	2,048	\$ (1,405,970)
LOSS PER SHARE					
Basic and diluted loss per share	(vi)	\$ (0.04)	\$	0.00	\$ (0.04)

# Reconciliation of Comprehensive Income for the Year Ended December 31, 2010

	Notes	Previous Canadian GAAP	Effect of transition to IFRS	IFRS
REVENUE				
Product sales		\$ 2,149,691	-	\$ 2,149,691
Contract manufacturing		850,613	-	850,613
Consulting services		1,358,521	-	1,358,521
		4,358,825	-	4,358,825
COST OF GOODS SOLD	(v)	2,614,919	18,069	2,632,988
GROSS PROFIT		1,743,906	(18,069)	1,725,837
0.41		100 710		400 = 40
Selling expenses	/··· o \	190,743	-	190,743
General and administrative expenses	(iii & v)	2,165,070	82,711	2,247,781
Product development and clinical trials expenses	(v)	1,820,688	21,455	1,842,143
Amortization	(v)	123,118	(123,118)	-
		4,299,619	(18,952)	4,280,667
OPERATING LOSS		(2,555,713)	883	(2,554,830)
OTHER INCOME (EXPENSES)				
Interest income		466	-	466
Interest on long-term debt		(11,567)	-	(11,567)
Loss on disposal of property and equipment		(9,912)	_	(9,912)
Loss on foreign exchange		(54,159)	-	(54,159)
3		(75,172)	-	(75,172)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		\$ (2,630,885)	\$ 883	\$ (2,630,002)
LOSS DED SHADE			·	
LOSS PER SHARE	/· ±\	¢ (0.07)	ф 0.00	¢ (0.07)
Basic and diluted loss per share	(vi)	\$ (0.07)	\$ 0.00	\$ (0.07)

# Material Adjustments to the Statement of Cash Flows for 2010

Consistent with the Company's accounting policy choice under IAS 7 Statement of Cash Flows, interest paid has moved into the body of the Statement of Cash Flows, whereas it was previously disclosed as supplementary information. There are no other material differences between the statement of cash flows presented under IFRSs and the statement of cash flows previously presented under Canadian GAAP.

# **Notes to the Reconciliations**

# (i) Presentation Differences

Certain presentation differences between Canadian GAAP and IFRS have no impact on comprehensive loss or total equity. Please see Notes (ii), (iv) and (v).

Under the "function of expense" presentation adopted for the Company's Statement of Comprehensive Loss under IFRS, depreciation expense is not presented as a separate line item, but is allocated to expense line items by function (see Note (v)).

In addition, amounts previously reported under "Product sales" have been disaggregated into "Product sales" and "Contract manufacturing" under IFRS (see Note (iv)).

Amounts previously reported under "Cash and cash equivalents" have been disaggregated into "Cash" and "Bank overdraft" under IFRS (see note (ii)).

# (ii) Bank Overdraft

Amounts previously reported under "Cash and cash equivalents" have been disaggregated into "Cash" and "Bank overdraft" under IFRS. Consequently, amounts reported as "Cash and cash equivalents" increased by \$186,897 as at January 1, 2010, by \$198,461 as at June 30, 2010, and by \$213,280 as at December 31, 2010 and amounts reported as "Bank overdraft" increased by \$186,897 as at January 1, 2010, by \$198,461 as at June 30, 2010, and by \$213,280 as at December 31, 2010.

# (iii) Share-Based Payments

Under Canadian GAAP, the fair value of share-based awards with graded vesting are calculated as one grant and the resulting fair value is recognized on a straight-line basis over the vesting period, with actual forfeitures recognized as they occur.

Under IFRS, each tranche of an award with different vesting dates is considered a separate grant for the calculation of fair value, and the resulting fair value is amortized over the vesting period of the respective tranches with forfeitures estimated at the date of grant, and updated at each subsequent reporting date.

As a result of applying the IFRS 2 to awards not yet vested at the date of transition to IFRS, contributed surplus was decreased by \$1,012 as at January 1, 2010 (June 30, 2010: decreased by \$3,060; December 31, 2010: decreased by \$1,895), and deficit decreased by \$1,012 as at January 1, 2010 (June 30, 2010: decreased by \$3,060, December 31, 2010: decreased by \$1,895); Share-based payment expenses in "General and Administrative Expenses" decreased by \$3,155 and \$2,048 for the three and six months ended June 30, 2010, respectively, and decreased by \$883 for the year-ended December 31, 2010.

#### (iv) Product Sales

Amounts previously reported under "Product sales" has been disaggregated into "Product sales" and "Contract manufacturing" under IFRS. Consequently, amounts reported as "Product sales" decreased by \$71,415 and \$431,902, and amounts reported as "Contract manufacturing" increased by \$71,415 and \$431,902 for the three and six months ended June 30, 2010, respectively.

# (v) Depreciation

Under IFRS, the Company has chosen to present the expenses recognized in profit or loss by their function. As a result, depreciation expense in Canadian GAAP is allocated to as an element of "Cost of goods sold", "General and administrative expenses" and "Product development and clinical trials expenses". As a result, amounts previously reported for these captions increased by \$4,414, \$21,043, and \$5,232 respectively for the three months ended June 30, 2010, increased by \$8,823, \$39,026, and \$10,298 respectively for the six months ended June 30, 2010, and increased by \$18,068, \$83,594, and \$21,455 respectively for the year-ended December 31, 2010.

# (vi) Basic and Diluted Loss Per Share

Basic and diluted earnings per share in 2010 are the same under IFRS as reported under Canadian GAAP.