



## CYTOMEDIX CEO ISSUES SHAREHOLDER UPDATE

**GAITHERSBURG, Md. (February 2, 2011)** – Cytomedix, Inc. (OTCBB: CMXI), (“the Company” or “Cytomedix”) a leading developer of biologically active regenerative therapies for wound care, inflammation and angiogenesis, today announced that Martin P. Rosendale, the Company’s President and Chief Executive Officer, issued the following letter to shareholders providing a general corporate update:

Dear Shareholders:

Having just completed a successful, important and transformative year for Cytomedix, I wanted to provide you with an update on our commercial progress and to set the stage for what we believe will be a year of exciting and notable developments for Cytomedix. At the outset, let me share with you a short list of projected milestones for the first half of 2011. Below in my comments, I will address most of these in further detail.

- Submit Medicare reimbursement reconsideration for wound care
- Submit FDA 510(k) application for enhanced AutoloGel™ PRP device
- Submit one FDA 510(k) application for a new Angel® indication
- Complete the Angel and activAT® manufacturing transition and transfer CE marks
- Continue to collect clinical data and publish two clinical articles

Most recently, we transitioned the trading of Cytomedix’s common stock to the over-the-counter markets, and the stock is now being quoted on the OTC Bulletin Board under our new ticker symbol of “CMXI.” First, I want to make clear that our fundamental business is no different today

under our new trading symbol than it was a week ago on the NYSE Amex. Having exhaustively considered various avenues available to us, we determined that the cost and dilution to the existing shareholders would have been unnecessarily excessive as we believe the capital required to execute on our business plan was already committed and available through our October 2010 registered direct offering and the \$11.5 million in financial commitments provided under two separate equity purchase agreements. We remain optimistic that the underlying liquidity in our stock can be maintained and we will do everything possible to promote continued transparency and visibility into our trading activity.

Let me turn now to Cytomedix's business progress, because it is these fundamental commercial and strategic developments that will impact our long term success.

As you are aware, the vast majority of my professional career has been spent in the commercialization of biologic therapies, specifically plasma proteins, blood derived products, and vaccines. What initially drew me to Cytomedix was a strongly held personal belief that this company's fundamental approach to the science and technology of tissue repair and rejuvenation is the correct approach. Therapies produced by the AutoloGel and Angel systems are based on the common premise that a complex combination of proteins, signal molecules and growth factors is necessary to address the highly complex biological mechanisms of interconnected molecular and cellular activity required to facilitate the regeneration of healthy tissue. With our technology platforms, we are working to harness the body's own naturally evolved regenerative mechanisms to promote better and faster clinical outcomes in a holistic manner as opposed to a narrowly-targeted approach. Much has been learned in the past 10-15 years concerning the vast role that plasma-derived proteins and related molecules play in molecular biology, with the promise of far more to come. We are actively engaged in these conversations with thought leaders and experts in the field, and fully expect to establish a leadership position in the evolving development of a deeper understanding of the underlying science and related clinical applications.

### Angel

The substantial overlap in technology and therapeutic mechanisms between the AutoloGel and Angel systems is what motivated our strategic decision to acquire the Angel product line from the Sorin Group last spring. With 9 months of ownership under our belt, we are very pleased with

our progress to date in integrating Angel into the Cytomedix business, and the potential we see for the asset in the months and years to come. Our experience with Angel, and growing familiarity with its strengths, supports our contention that it is truly a 'best in class' product in its market with product features and capabilities that set it apart from competing devices. This assertion stands in contrast to Angel's relatively modest single digit share in the marketplace and highlights a meaningful opportunity to not only grow with the market but to capitalize on a substantial market share opportunity. As we have discussed, our highest priority post-acquisition was to directly connect with the existing domestic Angel customers and ensure the continuation of those important revenue streams. While we experienced some small individual customer account losses in the transition, our net attrition has been zero and, in fact, Angel revenues are clearly up from their run-rate at the time we purchased the business from Sorin.

Today, we are actively prospecting new customers, winning new business under multi-year arrangements that benefit us now and in future periods, and have a full sales and evaluation pipeline. In addition to the direct Cytomedix sales force we have in the field, we are fortunate to have highly-skilled and long-term industry sales representatives operating independently and successfully to win new business. In combination with the expanded indications we intend to pursue this year, we believe our outlook for growth in Angel in the U.S. market is strong and sustainable.

In Europe, the Angel acquisition provided us with a mix of direct sales and small distribution arrangements in selected countries. Under the leadership of our international sales and marketing consultant, Michael Joos, we have embarked on a well-defined European expansion plan. In Europe, as well as in the U.S., we expect to benefit from the expertise of Dr. Peter Everts, a member of our recently formalized scientific advisory board. Dr. Everts is a world recognized expert in platelet rich plasma (PRP) and its associated clinical uses and, as a long time Angel user, will be instrumental in helping guide our product development and clinical strategies.

The transition of manufacturing and other related activities prevented us from giving the European opportunity our full attention at the outset. In December 2010, we were pleased to announce receipt of ISO 13485 Certification, which certifies Cytomedix as a provider of high-quality devices for the medical industry and allows the Company to operate commercially in Europe and in Canada. Moreover, we expect to complete the manufacturing transition and

transfer the CE Marks for Angel and activAT in the coming weeks. With these certifications secured, we can focus on expansion opportunities in the international markets which we believe can and will be a substantial contributor to overall Angel growth later in 2011 and into the future.

### AutoloGel and CMS Reimbursement

Our commercial revenues for the AutoloGel System posted healthy year-over-year growth figures, yet remain modest. However, this does not diminish our enthusiasm for its long term potential. 2011 will be a critical year for laying further groundwork that will help us realize this potential. In simple terms, AutoloGel works well - especially in the context of a market still facing a substantial unmet medical need where accepted clinical success in the treatment of non-healing chronic wounds is considered to be somewhere around 50%. Since completely reformulating the scientific and clinical message in early 2009, and effectively re-launching the product with a much more clinically intensive effort, we have essentially been pursuing three basic aims:

- 1) Educating a skeptical clinical community which has seen scores of wound care products that failed to deliver in real world clinical practice
- 2) Collecting critically important data to build a robust, verifiable and credible data set that can be appropriately analyzed, published and presented to healthcare providers and payers.
- 3) Focusing the above efforts primarily in markets dominated by prospective payment systems which will benefit from cost savings and clinical efficacy such as Long Term Acute Care and Veterans Hospital facilities

The educational efforts have been an unqualified success. In addition to establishing a growing collection of wound care clinicians who have experienced notable clinical success with their patients, the ongoing data collection continues to support and validate the clinical efficacy of AutoloGel as demonstrated in the pivotal, randomized, controlled trial that led to AutoloGel's marketing clearance from the FDA. From a reimbursement perspective, the shortcoming in that study was considered to be its relatively small size, notwithstanding its statistical significance. Consequently, a fundamental goal has been to collect high-quality data to validly demonstrate clinically relevant outcomes in a larger number of AutoloGel-treated patients. The core of this

expanded data set has been an ongoing wound registry populated by wounds of various etiologies at multiple clinical sites. It is further supplemented by data on 100 wounds from our post-market surveillance study and data from another 100 wounds collected by Millennia, our partners in Japan, in conjunction with their ongoing clinical and regulatory approval process in Japan. Throughout 2010, various aspects of this evolving data set have been published as peer-reviewed articles in industry journals and/or have been presented at various industry conferences and medical meetings. In the care settings where this registry has been collected, the outcomes have been consistent and unequivocally positive: *previously non-healing wounds can have their fundamental wound trajectory immediately and positively impacted to such a degree that over a short treatment period of approximately 3 weeks (the typical length of stay in these care facilities) the physical wound size in area and/or volume is significantly reduced.*

A subset of this data is currently in the final stages of manuscript preparation and is expected to be submitted for peer reviewed publication in the coming weeks. This data set is unique in that we were able to obtain the 'run-in' data for this subset of patients and, therefore, know the nature of their wound treatment prior to initiating AutoloGel treatment, its length and outcomes, and we can even estimate the cost of prior treatment. In essence, the run-in data provides the control for comparison and allows the data to be analyzed in that context. The analysis being applied to this data is novel and, in our opinion and that of the experts involved with us on this effort, is establishing an important new standard in terms of assessing clinically meaningful and relevant outcomes. The outcomes are highly statistically significant and we eagerly look forward to their publication later this year.

The ultimate outcome of efforts at health care reform may still be subject to debate, but it seems reasonably intuitive and obvious that greater cost effectiveness is a necessary condition of any overall solution. Based on previously published pharmacoeconomic studies, and more importantly, on data such as the article about to be submitted for review and publication, we strongly believe that an effective therapy such as AutoloGel can play an important role in providing cost effective outcomes to the health care system while delivering clinically meaningful and beneficial outcomes for patients.

This is the straightforward message we plan to convey to CMS during our upcoming reimbursement discussions. We are only modestly behind schedule with where we had hoped to

be in terms of actively engaging CMS on the topic of an official reimbursement reconsideration request for PRP for wound care. Our important focus has been and continues to be to 'get it right.' Our current expectation is to meet with CMS as soon as practical and to file the formal resubmission request shortly following that meeting. As previously discussed, if CMS agrees to a reconsideration, these actions begin a formal 180 day review process by CMS in advance of a preliminary determination. We would expect to meet again with CMS during that 180 day period where we will be joined by a collection of industry key opinion leaders and stakeholders for a comprehensive review of all the applicable data and literature (clinical and scientific). We are excited to engage in this process as we believe the data, clinical outcomes, and cost benefits all point toward a favorable conclusion that supports the reimbursement of this technology for the benefit of patients and the system as a whole.

Another significant development that promises to have a meaningful impact on clinical adoption of AutoloGel will be the planned introduction of the redesigned AutoloGel centrifuge - what we internally refer to as AutoloGel 2.0. The new device, developed with the assistance of some creative biomedical engineers in Israel, offers a completely proprietary means of plasma and platelet separation that is simpler and more straightforward than our current system. This streamlines the process and provides for a more aseptic environment that may be more conducive for certain developing orthopedic indications. At the point of care, we believe the improved ease-of-use will be of real benefit to treating clinicians and expect it to have a favorable impact on product adoption. Importantly, these new enhancements provide additional intellectual property opportunities for which we have already filed patent applications. The device and its components are in the required stages of validation and, based on anticipated feedback from the FDA, we expect to file for 510(k) marketing clearance in the coming three months.

### **Business Development Opportunities**

We currently have more business development opportunities in front of us than we have had cumulatively over the past couple of years. Most of these are inbound inquiries that are largely due to our heightened profile in the marketplace and within the broad arena of regenerative medicine. This enhanced visibility is mainly a result of our acquisition of Angel and, importantly, because the Angel product itself is drawing interest. With the integration of Angel

now well in hand, we are turning our full attention to these opportunities. We are very optimistic that we can succeed in delivering attractive agreements in the coming year that will offer strong third party validation of our approach to these markets. The range of potential opportunities is broad at this time and could range from expanded geographic distribution arrangements with larger companies interested in securing a PRP solution to more narrowly-targeted collaborations in areas of specific clinical interest. Clearly, the broad orthopedics area continues to garner interest and attention as access to clinical data and physician experience advances. Our early initiatives in the hair restoration market as well as early-stage discussions within the plastic surgery area also leave us encouraged about the potential for our PRP solutions in these growing markets.

### **In Closing**

We are very excited about the opportunities ahead for your Company as we continue to build on the clinical data and positive patient outcomes with our unique PRP products that harness the body's own naturally-evolved regenerative mechanisms to promote better and faster clinical outcomes. As an organization, we have a number of goals and objectives for 2011 and beyond, but our overriding and primary goal is to expand our footprint in our core markets and to drive sustainable growth in product sales for both Angel and AutoloGel. We are confident we have the right strategy in place to leverage the multitude of opportunities before us and we look forward to reporting to you on our progress in these areas. We thank you, our loyal shareholders, for your ongoing support and encouragement as we strive to make 2011 another transformative year for Cytomedix.

Sincerely,

*Martin P. Rosendale*  
President and Chief Executive Officer

### **About Cytomedix, Inc.**

Cytomedix develops, sells and licenses regenerative biological therapies primarily for wound care, inflammation and angiogenesis. The Company markets the AutoloGel™ System, a device for the production of platelet rich plasma (PRP) gel derived from the patient's own blood for use on a variety of exuding wounds; the Angel® Whole Blood Separation System, a blood processing

device and disposable products used for the separation of whole blood into red cells, platelet poor plasma (PPP) and PRP in surgical settings; and the activAT® Autologous Thrombin Processing Kit, which produces autologous thrombin serum from PPP. The activAT® kit is sold exclusively in Europe and Canada, where it provides a completely autologous, safe alternative to bovine-derived products. The Company is pursuing a multi-faceted strategy to penetrate the chronic wound market with its products, as well as opportunities for the application of AutoloGel™ and PRP technology into other markets such as hair transplantation and orthopedics while actively seeking complementary products for the wound care market. Cytomedix also seeks to monetize other product candidates in its pipeline through strategic partnerships, out-licensing or sale. Most notably is its anti-inflammatory peptide (designated CT-112) that has shown promise in preclinical testing. Additional information regarding Cytomedix is available at [www.cytomedix.com](http://www.cytomedix.com).

***Cautionary Note regarding Forward Looking Statements***

Statements contained in this communication not relating to historical facts are forward-looking statements that are intended to fall within the safe harbor rule for such statements under the Private Securities Litigation Reform Act of 1995. Such statements contained in this release are based on management's exercise of business judgment as well as assumptions made by and information currently available to management. When used in this document, the words "may", "will", "anticipate", "believe", "estimate", "expect", "intend", and words of similar import, are intended to identify any forward-looking statements. The information contained in the forward looking statements is inherently uncertain, and Cytomedix's actual results may differ materially due to a number of factors, many of which are beyond Cytomedix's ability to predict or control, including among others, viability and effectiveness of our sales approach and overall marketing strategies, the outcome of development or regulatory review of CT- 112, our ability to accomplish the stated objectives with respect to the CMS coverage and timing of such process, commercial success or acceptance by the medical community, competitive responses, our ability to raise additional capital and to continue as a going concern, our ability to execute on our strategy to market the AutoloGel™ System as contemplated, our ability to successfully integrate the Angel® and activAT® product lines into our existing business, to assume and satisfy certain liabilities related to the Angel® and activAT® product lines, or our ability to service the deferred payments related to the acquisition of the Angel® and activAT® product lines. These forward-looking statements are subject to known and unknown risks and uncertainties that could cause actual events to differ from the forward-looking statements. More information about some of these risks and uncertainties may be found in the reports filed with the Securities and Exchange Commission by Cytomedix, Inc., as such filings have been amended and updated to date. Cytomedix operates in a highly competitive and rapidly changing business and regulatory environment, thus new or unforeseen risks may arise. Accordingly, investors should not place any reliance on forward-looking statements as a prediction of actual results. Except as is expressly required by the federal securities laws, Cytomedix undertakes no obligation to update or revise any forward looking statements, whether as a result of new information, changed circumstances or future events or for any other reason.

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