# From Bankruptcy to Success Through Licensing: The Cytomedix Story

Steve Jakubowski, Esq., The Coleman Law Firm Jeff Snell, CRA International

LES Winter Meeting Managing the Evolving Deal

> San Francisco, CA February 22, 2007 1:45 p.m. -3:00 p.m.

### The Market Need

#### **Diabetic Foot Ulcer**



#### **Venous Stasis Ulcer**



### The Market Potential

#### **Chronic wounds**

<b>Worldwide</b>	<u>U.S.</u>

Venous stasis ulcers 4,000,000 900,000

Diabetic foot ulcers 6,000,000 1,500,000

- Over 82,000 U.S. amputations/year!

Pressure ulcers

8,000,000

2,100,000

 Infection from a pressure ulcer was the cause of actor Christopher Reeve's death

### The Opportunity

# Navigating Bankruptcy

#### New Business Model

- Knighton patent
- Procuren product line
- Denial of reimbursement for Procuren
- Worden improvement
- Procuren put up for sale
- Cytomedix acquires Procuren and Knighton patent

- Post acquisition collapse
- DePuy license
- Liquidation of Procuren centers
- Financing death spiral
- Filing for bankruptcy
- Shareholders halt BK auction and take control of DIP
- Court confirms reorg. plan

- Commercialize AutoloGel in wound care
- Aggressive enforcement of patent rights
- Development of licensing strategy
- Key financial issues
  - -Prior use
  - -Separate royalty for equipment and disposables

- DePuy constraints
- License agreements
- Key terms
  - -Fields of use
  - -Assignability
  - Most Favored Nation
  - -Adverse Rulings
  - -Public Disclosure
  - -Markings/Advertising

### Knighton Patent Claims – 5,165,938

#### What is claimed:

- A process for treating damaged, live, animal tissue which comprises applying over the damaged tissue an <u>effective amount</u> of treating composition containing the <u>materials released by platelets</u> during the platelet release reaction and <u>facilitating healing of the damaged tissue</u>.
- 2 The method in claim 1 wherein the materials are applied topically in an amount sufficient to cause migration and/or division of fibroblast cells, capillary endothelial cells, and/or epithelial cells.
- 8 The method of claim 7 (wherein the platelets are <u>human platelets</u>) wherein prior to release of the material said platelets were <u>removed from the person whose tissue is being treated</u>.
- 10 The method in claim 1 wherein the materials are released from said platelets by <u>use of an activator</u> selected from the group consisting of thrombin, adenosine diphosphate and collagen.

(Emphasis added)

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### Reimbursement Decision

11-94

COVERAGE ISSUES - SUPPLIES DRUGS

45-27

#### 45-26 PLATELET-DERIVED WOUND HEALING FORMULA--NOT COVERED

A platelet-derived formula containing growth factors intended to treat nonhealing wounds (e.g., Procuren) is provided through hospital-based outpatient facilities as part of comprehensive wound-care programs designed to treat patients with chronic nonhealing wounds. It is usually applied at first in the presence of a physician, with the patient continuing applications at home. There is a lack of sufficient published data to determine the safety and efficacy of the platelet-derived wound healing formula (based on a technology review by the Public Health Service). Therefore, it is not covered under Medicare because it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

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# Curative Royalty Agreement

#### OVALTY ACREMENT

This Royalty Agreement (the "Agreement"), is made and entered into as of 

Declaration 36, 2000 (the "Effective Date"), by and between Cytomedix, inc., a Delaware corporation ("Cytomedix"), and Curative Health Services, inc., a Minnesota corporation ("Curative").

#### RECITALS

WHEREAS, Cytomedix and Curative are parties to that certain Amended and Restated Asset Purchase Agreement effective as of October 12, 2000 (the "Asset Purchase Agreement"), pursuant to which Cytomedix has agreed to purchase certain assets of Curative and its Affiliates as set forth therein; and

WHEREAS, pursuant to Section 2.7(a)(viii) of the Asset Purchase Agreement, it is a condition to the closing of the transactions described in the Asset Purchase Agreement that the parties hereto enter into this Agreement

#### AGREEMENT

NOW, THEREFORE, for and in consideration of the premises and the mutual covenants contained herein, and for other good and valuable consideration, the receipt, adequacy and legal sufficiency of which are hereby acknowledged, the parties do hereby agree as follows:

#### ARTICLE I.

For purposes of this Agreement, the following terms and variations thereof have the meanings specified or referred to in this Article I:

"Affiliates" – any person or entity which directly or indirectly controls, is controlled by, or is under common control with a party hereto. For purposes of this Agreement, "control" means the legal, beneficial or equitable ownership directly or indirectly of more than 50% of the aggregate of all voting equity interests rights in such entity.

"Best Effort" – the efforts that a prudent person desirous of achieving a result would use in similar circumstances to ensure that such result is achieved as expeditiously as possible; provided, however, that a person required to use Best Efforts under this Agreement will not be required to dispose of or make any change to its business, or expend any material funds or incur any other material burden.

" $\overline{\text{FDA}}$ " – the United States Food & Drug Administration, or any successor agency.

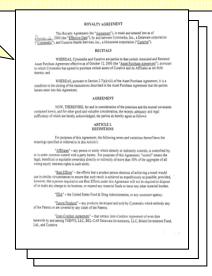
"Future Products" – any products developed and sold by Cytomedix which embody an of the Patents or are covered by any claim of the Patents.

"Inter-Creditor Agreement" – that certain Inter-Creditor Agreement of even date herewith by and among TSENVI, LLC, BEL-CAP Delaware Investments, LLC, Bristol Investment Fund, Ltd., and Curative. (b) Cytomedix shall pay Curative six percent (6%) (the "Future Products Rovalty Percentage") of the aggregate Net Sales Amount of the Future Products (the "Future Products Rovalty," and together with the Procuren Royalty, the "Rovalty"), on a country by country basis, in each Applicable Country for such time as any of the Patents with respect to such Applicable Country remain valid, enforceable, and in effect; provided, however, that at such time that the aggregate worldwide Net Sales Amount of the Future Products with respect to which the Future Products Royalty has been paid since the Effective Date exceeds Three Hundred Million Dollars (\$300,000,000), the Future Products Royalty Percentage shall thereafter be reduced to five percent (5%). Cytomedix shall have no further obligation to pay the Future Products Royalty in any Applicable Country at such time that no Patent with respect to such Applicable Country remains valid, enforceable and in effect.

# Curative Royalty Agreement

Section 6.1 <u>Security Interest</u>. Subject to the applicable terms and conditions of this Agreement, Cytomedix hereby assigns and grants to Curative a security interest (the "<u>Security Interest</u>") in and a lien on the Patents (the "<u>Collateral</u>") to secure the payment and the performance of the following obligations (collectively, the "<u>Obligations</u>"):

- (a) the payment of the Royalty; and
- (b) all reasonable costs incurred by Curative to obtain, preserve, perfect and enforce the provisions of this Article VI and the Security Interest created hereby, collect the Royalty and maintain and preserve the Collateral, including but not limited to taxes, assessments, insurance premiums, repairs, reasonable attorney's fees and legal expenses, and expenses of sale.



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A small amount of a

patient's blood is drawn



Source: http://www.cytomedix.com/270,15,The AutoloGel™ System

The tubes of blood are placed into a centrifuge machine



Source: http://www.cytomedix.com/270,15,The AutoloGel™ System

The platelets and plasma are separated from the whole blood



Source: http://www.cytomedix.com/270,15,The AutoloGel™ System

Reagents are added to the platelet-rich plasma (PRP) to activate the platelets, causing:

- the release of multiple growth factors
- creation of a fibrin matrix scaffold
- the PRP liquid to transform into a gel



Source: http://www.cytomedix.com/270,15,The AutoloGel™ System

The resulting gel, AutoloGel™, is applied topically to the patient's wound



Source: http://www.cytomedix.com/270,15,The AutoloGel™ System

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#### Aggressive Enforcement of Patent Rights

- 3I Implant Innovations
- ABI Extracorporeal
- ABR Inc.
- Advanced Blood Recovery, Inc.
- Advanced Cosmetic Surgery and Laser Center of Hyde Park
- Advanced Cosmetic Surgery Center
- Advanced Facial Cosmetic & Laser Surgery Center, Inc.
- Advanced Perfusion Care, Inc.
- Arizona Blood Management, Inc.
- Arizona Blood Therapies, LLC
- Autologous Blood Services, LLC
- Autologous Blood Technology
- Autotransfusion, Inc.
- B&B Autotransfusion Services, Inc.
- Bennett Medical
- Dr. Keith Bennett
- Blood Recovery Systems, Inc.
- Mr. Bill Brown
- Carter Blood Care
- Center for Facial Cosmetic Surgery
- Chiron Corporation
- Clinical Cardiac Perfusion, Inc.
- Coastal Cardiovascular Services, LLC
- Cobe Cardiovascular
- Cohesion
- Contran
- Cooper Health System
- Corazon

- Dermatology Specialists of Naples
- Direct Medical Co.
- Diversified Therapies
- Fresenius Medical Care North
- Gambro BCT (formerly Cobe)
- Mr. James Gandy
- GELTECH, Inc.
- H & M Medical Services, Inc.
- Haema-Gel Services
- Haemonetics
- Hamot Health System
- Harvest Technology Corp
- Heart of America Medical
- Hemoserv Inc.
- Hinsdale Blood Component Collection Center
- Implant Dentistry of Washington
- Integrated Blood Services, Inc.
- Internal Medicine Associates Infusion Centers
- Interpore Cross International
- La Piel Face Spa
- Life Care, Inc.
- Life-Cor Perfusion Resources, Inc.
- Lifesource Technologies, Inc.
- Dr. Daniel Man
- Medtronic
- Metro Preferred
- Naples Facial Plastic Surgery
- OCT USA, Inc. dba OSCOTEC

- Oral and Maxillo-Facial Surgeon
- Pacific Auto Transfusion Corp.
- Pacific Life Systems, Inc.
- Palm Beach Hair Institute
- Palm Beach Institute of Cosmetic Surgery
- Perfusion Management Group, Ltd.
- Perfusion Partners and Associates, Inc.
- Physicians Skin Care & Facial Plastic Surgery
- Physiologic Reps, Inc.
- PlasmaSeal
- Platelet Gel Services
- Platelet Rich Services
- PPAI Medical
- Prosthodontics Inermedica
- Dr. Rene Ranieri
- Riverside Plastic Surgery & Sinus Center
- Riverview Hospital
- SafeBlood Technologies
- Salvin Dental
- Seattle Implants
- Southwest Hospital
- Dr. E. Prince Stover
- Trinity Medical Services
- Turning Point
- West Texas Profusion
- Wound Care Center and Brevard Regional Hyperbaric Center

Source: Disclosure Statement to the First Amended Plan of Reorganization of Cytomedix, Inc., Appendix F.

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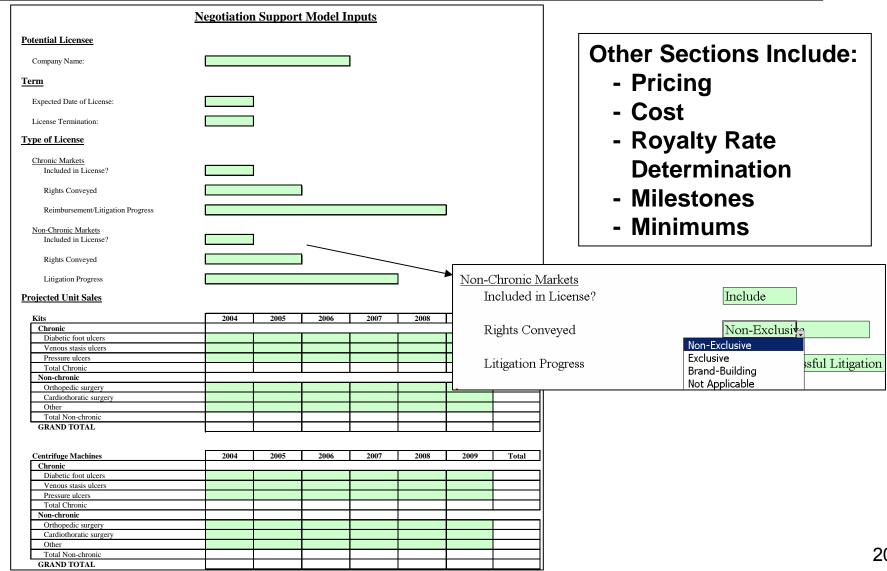
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#### Valuation Issues

- What is our technology worth?
- > How do we deal with the uncertainties?
  - Ability to segment the market
  - Reimbursement for AutoloGel
  - Litigation outcomes

### Flexible Licensing Model - Assumptions



### Royalty Rate Determination

- Comparable license agreements
  - Wound healing treatments
  - Existing agreements for platelet gel
- Profit apportionment
  - Projected AutoloGel profitability
  - Profitability of platelet gels
  - Industry profitability
- Alternatives

### Flexible Licensing Model – Term Sheet

#### **Internal Term Sheet: License to Cytomedix Technology**

Licensee:

Company Name

Key Points to Highlight:

- Success of Cytomedix's technology depends on licensee efforts, so Cytomedix requires performance guarantees (lump sum or minimums).
- 2. Progress of clinical trials.
- 3. Progress in receiving Medicare reimbursement.
- 4. Efficacy.
- 5. Ease of use.
- 6. Breadth of patent coverage.

	2004	2005	2006	2007	2008	2009	Total
Projected Licensee Revenue:							
Kits - Chronic	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
Kits - Non-Chronic	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
Centrifuge Machines - Chronic	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
Centrifuge Machines - Non-Chronic	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
Total Projected Licensee Revenue	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
NPV of Projected Running Royalties	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX
Lump Sum Payment: -OR-	\$XXX	* To be credited	l against running	royalties.			
	2004	2005	2006	2007	2008	2009	Total
Minimum Payments:	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX	\$XXX

Kits - Chronic

Kits - Non-Chronic

Centrifuge Machines - Chronic

Centrifuge Machines - Non-Chronic

 May consider negotiated fixed payments for the successful completion of clinical trials, FDA approval, Medicade/Medicare reimbursement, etc.

Milestone Payments:

- X years

X.X%

X.X%

X.X%

X.X%

Term (years): Fields of Use:

- If possible, limit license to specific market applications based on outcome of analysis of indications and licenseebusiness activity.

Grant Backs:

- Consider negotiating a royalty-free license to any improvements developed by licensee.

Most Favored Nation:

- Ensures a licensee that it is paying the lowest rate among all licensees.

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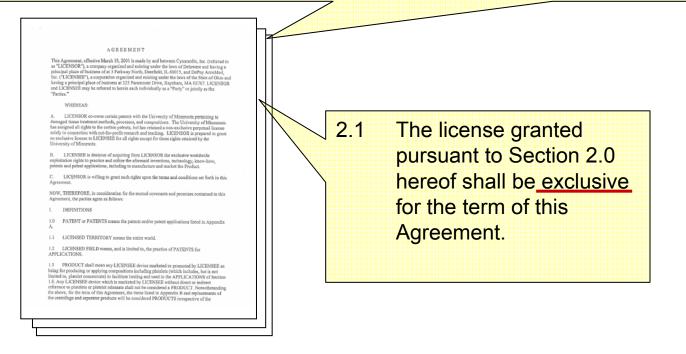
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### DePuy Constraints: Exclusivity

1.5 APPLICATIONS shall mean diagnostic and therapeutic spinal, neurosurgery (including cranial), orthopaedic (including joint replacement, sports medicine and trauma) surgeries, including soft tissue damage resulting from such surgeries. APPLICATIONS excludes soft tissue applications outside of such surgeries, including chronic non-healing wounds; dental applications; and veterinary applications.. The term "soft tissue" means any tissue other than bone, joint, cartilage, ligaments, and tendons. The term "chronic non-healing wounds" means wounds lasting 30 days or longer.



### DePuy Constraints - Royalties

3.0 LICENSEE shall, as a license fee, pay to LICENSOR within five (5) business days of the effective date of this Agreement, seven hundred and fifty thousand dollars (\$ 750,000), which shall be nonrefundable and not creditable against the royalty called for under Section 3.1.

#### AGREEMENT

This Agreement, effective March 19, 2001 is made by and between Cytomedix, Inc. (referred to as "LICENSOR"), a company organized and existing under the laws of Delaware and having a principal place of business of at 3 Parkway North, Deerfield, IL 60015, and DePuy AcroMed, Inc. (\*LICENSEE"), a corporation organized and existing under the laws of the State of Ohio and having a principal place of Dusiness at 325 Paramount Drive, Raynham, Ma 02767. LICENSOR and LICENSOE may be referred to herein each individually as a "Party" or jointly as the "Parties."

#### WHEREAS

- A. LICENSOR es-owns certain patents with the University of Minnesota pertaining to managed fisuse tentament methods, processes, and compositions. The University of Minnesota has assigned all rights to the certain patents, but has retained as new excellent in the proposal license solely in connection with not-for-profit research and teaching. LICENSOR is prepared to grant an exclusive license to LICENSEE for all rights except for those rights retained by the University of Minnesota.
- B. LICENSEE is desirous of acquiring from LICENSOR the exclusive worldwide exploitation rights to practice and utilize the aforesaid inventions, technology, know-how, patents and patent applications, including to manufacture and market the Product.
- LICENSOR is willing to grant such rights upon the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration for the mutual covenants and promises contained in this Agreement, the parties agree as follows:

- I. DEFINITION
- 1.0 PATENT or PATENTS means the patents and/or patent applications listed in Appendix
- 1.1 LICENSED TERRITORY means the entire world.
- 1.2 LICENSED FIELD means, and is limited to, the practice of PATENTS for APPLICATIONS.
- 1.3 PRODUCT shall mean any LICENSEE device marketed or promoted by LICENSEE as being for producing or applying compositions including platelets (which includes, but is not limited to, platelet concentrate) to facilitate heating and used in the APPLICATIONS of Section 1.8. Any LICENSEE device which is marketed by LICENSEE without direct or indirect reference to platelets or platelet releastes shall not be considered a PRODUCT. Notwithstanding the above, for the term of this Agreement, the tiens listed in Appendix B and replacements of the centrifuge and Separator products will be considered PRODUCTS inspective of the

3.1 LICENSEE shall pay to LICENSOR six and one half percent (6.5 %), after the effective date, of the NET SALES PRICE ("Royalty") of all PRODUCTS sold or otherwise disposed of under the license granted under Section 2.0 of this Agreement in jurisdictions having valid unexpired, and enforceable U.S. or foreign PATENTS where PRODUCT is made, used, sold, or offered for sale.

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# License Agreements

Licensee	Date of Agreement	Date of Expiration	Lic	Initial censing Fee	On-going Royalty Percentage
DePuy Spine, Inc.	3/19/01 3/4/05	11/24/09	\$	750,000	6.5%
Medtronic, Inc.	5/1/05	11/24/09	\$	680,000	7.5% on disposables 1.5% on hardware
Harvest Technologies, Inc.	5/23/05	11/24/09	\$	500,000	7.5% on disposables 1.5% on hardware
Perfusion Partners, Inc.	6/26/05	11/24/09	\$	250,000	10%
COBE Cardiovascular, Inc.	10/7/05	11/24/09	\$	45,000	7.5% on disposables 1.5% on hardware
SafeBlood Technologies, Inc.	10/12/05	11/24/09	\$	50,000	8.0% to 9.0%
Biomet Biologics, Inc.	5/19/06	11/24/09	\$	2,600,000	none

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#### Field of Use

DePuy – 2<sup>nd</sup> Agreement

1.02 ADDITIONAL LICENSED FIELDS means all fields other than (i) the LICENSED FIELD of the FIRST LICENSE AGREEMENT and (ii) the treatment of "chronic non-healing wounds." For purposes of this SECOND LICENSE AGREEMENT, the term "chronic non-healing wounds" means (i) any venous stasis, decubitus, or diabetic foot ulcers or (ii) any wounds lasting 30 days or longer.

- Harvest 1.13 "Licensed Fields" means any and all fields of use.
  - Cobe 1.12. "LICENSED FIELDS" means any and all fields of use.
- Medtronic 1.10. "LICENSED FIELDS" means any and all fields of use, worldwide.

**Biomet** 

1.8. "BIOMET LICENSED FIELDS OF USE" means any and all fields of use except Biomet shall not market BIOMET BRANDED PRODUCTS in the field of chronic, non-healing wounds that last 30 days or more.

#### **PPAI**

therewith.

2.1. Licensed Patent Rights. Cytomedix hereby grants to Licensees for the term specified in Section 5.1 hereof, a non-exclusive, royalty-bearing license to manufacture, have made, use, import, sell, promote, market offer for sale, or otherwise transfer PPAI Branded Platelet Products for use in practicing processes covered by one or more claims of the Licensed Patents in any field of use anywhere in the world. This grant includes the right for Licensees to grant sublicenses to Distributors, with the prior written consent of Cytomedix (which shall not be unreasonably withheld). This grant also includes the right for any customers (ultimate or in privity or otherwise) of Licensees or Distributor import, market, offer for sale, and/or s ...any field of use Products without payment of any ad license grant "runs with the PPAI Bra anywhere in the Branded Disposable Kit is used in ea the Licensed Patents shall be exhaus Product as to which the required re world. Agreement, the limited license grant s as the "Licensed Patent Rights." Licensees snall have no right to perform a Platelet

Service unless a single use PPAI Branded Disposable Kit is used in conjunction

#### SafeBlood

- License Grant.
- Licensed Patent Rights. Cytomedix hereby grants to SafeBlood for the term specified in Section 6.1 hereof, a non-exclusive, royalty-bearing license to manufacture, have made, use, import, sell, promote, market, offer for sale, or otherwise transfer Platelet Products, Activated Platelet Gel Services and Experimental Platelet Gel Therapies for use in practicing or involving the practice of processes covered by one or more claims of the Licensed Patent in any field of use. This grant includes the right for any customers or Distributors (ultimate or in privity or otherwise) of SafeBlood to use import, market, offer for sale, and/or sell (for further use or resale) Platelet Products purch or indirectly from SafeBlood without pa ...in any field of Cytomedix. This license grant "runs wi Patent shall be exhausted with respect to ired royalty hereunder is paid. For purposes use. t set forth in this Section 3.1 is hereinafter re

# Assignability (1 of 4)

#### DePuy – 2<sup>nd</sup> Agreement

#### NONASSIGNABILITY

13.00 This Agreement or any interest herein shall not be assigned or transferred, in whole or in part, by either party hereto without the prior written consent of the other party hereto. However, without securing such prior written consent, either party may assign this Agreement to an AFFILIATE or a successor of all or substantially all of its business to which this Agreement related provided, that no such assignment shall be binding and valid until and unless the assignee shall have assumed in a writing, delivered to the non-assigning party, all of the duties and obligations of the assignor. If the LICENSEE is the assignor, then the LICENSEE shall remain liable and responsible to the non-assigning party hereto for the performance and observance of all such duties and obligations. If the LICENSOR is the assignor, the LICENSOR shall give written notice to LICENSEE of any assignment of any of the PATENTS.

#### **PPAI**

9.4. Assignment. Licensees may not assign any of their respective rights or obligations under this Agreement to any person or entity without prior written consent of Cytomedix. Cytomedix may assign its rights under this Agreement in its sole and absolute discretion.

#### SafeBlood

10.4. Assignment. SafeBlood may not assign any of their respective rights or obligations under this Agreement to any person or entity without prior written consent of Cytomedix, which may not be unreasonably withheld. Cytomedix may assign its rights under this Agreement in its sole and absolute discretion.

Medtronic 11.3 Assignment. This Agreement and any of the rights and obligations thereof are fully assignable by both Parties.

### Assignability (2 of 4)

10.3 <u>Assignment</u>. This Agreement and any of the rights and obligations thereof are fully assignable by both Parties, and further subject to the following:

#### Cobe

- 10.3.1 In the event of an assignment by Cobe (whether by operation of law, merger, acquisition or change of control) (an "Assignment"), CYTOMEDIX shall be paid by Cobe or said assignee cash in an amount equal to the sum of 1% of the Gross Price of all Hardware Products plus 5% of the Gross Price of all Disposable Products sold by said assignee prior to the Effective Date of this Agreement, regardless of whether such products are currently marketed by assignee within thirty (30) days of the effective date of the Assignment.
- 10.3.2 In the event (i) an Assignment occurs, and (ii) the assignee or one of its Affiliates has an agreement with CYTOMEDIX granting a license to one or more of the Licensed Patents (the "Assignee License Agreement"), CYTOMEDIX hereby agrees that the Assignee shall not be in breach of the Assignee License Agreement or this Agreement so long as it complies, on a licensed product-by-licensed product basis, with the terms and conditions of the Assignee License Agreement or the terms and conditions of this Agreement. The assignee shall not be considered to have failed to comply with respect to a particular product under the Assignee License Agreement or this Agreement on the basis of the field of use so long as assignee (1) makes a good faith judgment either on an invoice-by-invoice basis or by reasonable means (such as allocation) as to which agreement covers particular sales of a particular product and (2) pays the royalty due under the agreement it has determined in good faith to cover the particular sales of the particular product. For the avoidance of doubt, if assignee determines in good faith that both agreements cover particular sales of a particular product, it may select to pay the royalty under either agreement. For the further avoidance of doubt, only one royalty shall be payable in respect of the sale of a given unit of a particular product.

# Assignability (3 of 4)

#### Biomet

7.4

Assignment. This AGREEMENT and any of the rights and obligations thereof are assignable by both Parties to an assignee of, acquirer of, or successor to (any of the foregoing a "Successor") (i) fifty percent (50%) or more of the assigning Party's stock, assets or business, or (ii) substantially all the assigning Party's assets of product line or business that includes one or more of the Licensed Biomet Products or the Licensed Cytomedix Products and further subject to the following:

- 7.4.1 In the event of an assignment by BIOMET, all remaining payments owing under Section 3.1 hereof shall be accelerated and CYTOMEDIX shall be paid by BIOMET or said assignee cash in an amount equal to remaining unpaid license fees payable under Section 3.1 hereof.
- 7.4.2 The scope of the license granted by CYTOMEDIX in Section 2.1 to any such successor shall be limited only to the LICENSED BIOMET PRODUCTS existing at the at the time of acquisition by the successor, and derivative products, and shall not extend to any past, present or future products of the successor in existence at the time of the acquisition or otherwise developed independently of the LICENSED BIOMET PRODUCTS acquired from BIOMET.

# Assignability (4 of 4)

1.3 <u>Assignment.</u> This Agreement and any of the rights and obligations thereof are fully assignable by both Parties.

#### Harvest

- 11.3.1 In the event of an assignment by Harvest (whether by operation of law, merger, acquisition or change of control) (an "Assignment"), Sections 3.2, 3.3 and 3.5 shall not apply to past, present, or future actions for or claims of infringement against any of the Assignee Parties in respect of an unlicensed product that infringes any Claim of one or more Licensed Patents (whether based on direct or contributory infringement, inducement to infringe or any other theory). Further, Section 3.4 shall not apply to the Assignee Parties. "Assignee Parties" shall mean the assignee, and its predecessors, successors and assigns, and its and their respective Affiliates. sublicensees. officers. directors, employees, shareholders, partners, representatives, and all other persons acting by or on its or their behalf.
- 11.3.2 In the event (i) an Assignment occurs, and (ii) the assignee or one of its Affiliates has an agreement with Cytomedix granting a license to one or more of the Licensed Patents (the "Assignee License Agreement"), Cytomedix hereby agrees that the Assignce shall not be in breach of the Assignee License Agreement or this Agreement so long as it complies, on a licensed product-by-licensed product basis, with the terms and conditions of the Assignee License Agreement or the terms and conditions of this Agreement. The assignee shall not be considered to have failed to comply with respect to a particular product under the Assignee License Agreement or this Agreement on the basis of the field of use so long as assignee (1) makes a good faith judgment either on an invoice-by-invoice basis or by reasonable means (such as allocation) as to which agreement covers particular sales of a particular product and (2) pays the royalty due under the agreement it has determined in good faith to cover the particular sales of the particular product. For the avoidance of doubt, if assignee determines in good faith that both agreements cover particular sales of a particular product, it may select to pay the royalty under either agreement, For the further avoidance of doubt, only one royalty shall be payable in respect of the sale of a given unit of a particular product.

### Most Favored Nation Clause

#### Medtronic

5.1. Most Favored Licensec. If Licensor enters or has entered into a license agreement involving any Licensed Patent with any Entity other than Medtronic or DePuy Inc., ("Other License"), then Licensor will, within one (1) month after the effective date of the Other License agreement or this Agreement (whichever is later), provide Medtronic with a confidential copy of the Other License agreement. Medtronic shall, at its option, be entitled at any time during the life of any said Other License to substitute, effective as of the effective date of the Other License, the royalty rate terms and conditions of said Other License agreement for the royalty rate terms and conditions of this Agreement. The Parties shall cooperate in good faith in making any refund or payment adjustment required in the event of such royalty rate substitution.

other than DePuy

#### Harvest

Most Favored Licensee. If, after the Effective Date of this Agreement, Licensor enters into a license agreement with any for-profit Entity (other than those providing direct medical care) that manufactures, markets or sells medical devices involving any Licensed Patent ("Other License"), then Licensor will, within one (1) month after the effective date of the Other License agreement or this Agreement (whichever is later), provide Harvest with a confidential copy of the Other License agreement for review by Harvest's officers and directors, attorneys, and financial advisors only. Harvest shall, at its option, be entitled at any time during the life of any said Other License to substitute, effective as of the effective date of the Other License, the royalty rate (and terms and conditions related thereto) of said Other License agreement for the royalty rate (and terms and conditions related thereto) of this Agreement. The Parties shall cooperate in good faith in promptly making any refund or payment adjustment required in the event terms or conditions of an Other License agreement are substituted pursuant to this Section.

any for-profit Entity (other than those providing direct medical care)

#### Cobe

4.1. Most Favored Licensee. If CYTOMEDIX enters into a license agreement involving any Licensed Patent with any Entity other than any Entity with whom CYTOMEDIX already has entered into a license agreement (hereinafter, an "Other License"), then CYTOMEDIX will, within two (2) months after the effective date of the Other License agreement or this Agreement (whichever is later), provide COBE with a confidential copy of the Other License agreement for review by COBE's officers and directors, attorneys, and financial advisors only; provided, however, that if the Other License is filed by CYTOMEDIX with the SEC without redaction as to the royalty rate terms and conditions in said Other License, then CYTOMEDIX shall be deemed to have complied with such delivery requirements. COBE shall, at its option, be entitled at any time during the life of any said Other License to substitute, effective as of the effective date of the Other License, the royalty rate terms and conditions of said Other License agreement for the royalty rate terms and conditions of this Agreement. The Parties shall cooperate in good faith in making any refund or payment adjustment required in the event of such royalty rate substitution.

any Entity other than any
Entity with whom
CYTOMEDIX already has
entered into a license
agreement

Note: No MFN clause in Biomet or service provider licenses

### Adverse Rulings

#### SafeBlood

- 5.5. SafeBlood shall be entitled to discontinue any royalty payments under this Agreement immediately upon the occurrence of the following with respect to all claims of the Licensed Patent:
  - 5.5.1 In any reexamination, reissue or court proceeding of the Licensed Patent, entry of a judgment, order, decree or decision to the effect that: (A) all of the claims of the Licensed Patent are invalid or otherwise unenforceable; or (B) the use of activated platelet gel therapies (or the manufacture, sale, offer for sale, or use of products substantially equivalent to the royalty-bearing products) to facilitate healing of human wounds or human tissue infringes none of the claims of the Licensed Patent, or
  - 5.5.2. Cytomedix expressly and in writing disclaims or abandons any independent claim of the Licensed Patent, or
  - 5.5.3. Claims in the Licensed Patent are disallowed or so substantially narrowed in any reexamination proceeding, such that the royalty-bearing products would be rendered non-infringing.
- 5.6. In the event Cytomedix obtains reversal of any adverse determination in Section 5.5.1. or 5.5.3. hereof that enabled SafeBlood to discontinue any royalty payments, then SafeBlood shall resume royalty payments affected thereby, and pay Cytomedix any royalties that accrued between suspension and resumption of royalty payments. Under no circumstances shall SafeBlood's obligation to Cytomedix to make royalty payments extend to sales made beyond November 24, 2009.

- Similar language in Medtronic, Harvest, and Cobe license agreements
- No adverse rulings clause in the DePuy, Biomet, and PPAI licenses

#### Public Disclosure

#### **Biomet**

Similar language in all other license agreements, except DePuy

Press Release: The Parties may issue a press release reporting, without limitation, that the Parties have resolved their disputes related to '938 Patent to their mutual satisfaction and that a license has been granted as part of this resolution, provided the Party intending to issue a press release shall give the other Party at least two business days to review the proposed press release and provide comments that shall, if reasonable, be incorporated into the actual press release. It is Cytomedix's intention, consistent with past practice, to file this Agreement with the SEC, without redaction, as a contract material to its business.

#### Harvest

6.2 Press Release. Each Party may state, in whole or in part, only the following with respect to the other Party, this Agreement, and the Massachusetts Action (the exact words need not be used, provided the substance is the same): "(1) The Parties have resolved the dispute related to the litigation to their mutual satisfaction, (2) the lawsuit has been dismissed, and/or (3) a license has been granted as part of the settlement."

# Markings/Advertising

#### DePuy – 2<sup>nd</sup> Agreement

#### XXII. MARKING

22.00 To the extent legally permissible and/or legally mandated, LICENSEE agrees to mark its brochures for the items listed in **Appendix BB** (revised and attached hereto) and improvements thereof with the following: "Certain products shown in this brochure are sold subject to a License Agreement with Cytomedix Inc., and are not licensed for use in treating chronic non-healing wounds (meaning any venous stasis, decubitus, or diabetic foot ulcers, or any other wounds lasting 30 days or longer); provided, however, that LICENSEE may use its existing stock of brochures (which lack said specific markings) until depleted.

#### **PPAI**

4.5. Advertising. PPAI owns and develops various internet sites and domains, including The Platelet Gel Network and website <a href="http://www.plateletgel.net">http://www.plateletgel.net</a> (collectively, whether now existing or hereinafter designed or created, the "Websites"). PPAI also owns, operates, or manages, in whole or in part, various educational and training facilities and programs, including The Florida Platelet Gel Symposium (collectively, whether now existing or hereinafter designed or created, the "Symposia"). Cytomedix will be invited to participate in all future Symposia as a presenter and/or exhibitor for wound care products and topics. At no time shall PPAI permit parties to advertise, promote, market, or sell their products or services on or in any of the Websites or Symposia unless said parties are authorized licensees, distributors, or sales representatives of Cytomedix.

#### Some Lessons Learned

- View bankruptcy as a possible solution instead of a last resort because decisions made to avoid bankruptcy may well be far worse than the bankruptcy process itself.
- Employ flexible financial models that can be adapted to different licensing partners and changing conditions throughout the execution of a licensing strategy.
- When negotiating off existing forms, carefully reexamine each provision in light of the human and business realities presented.