

# CryoLife Inc. Corporate Presentation

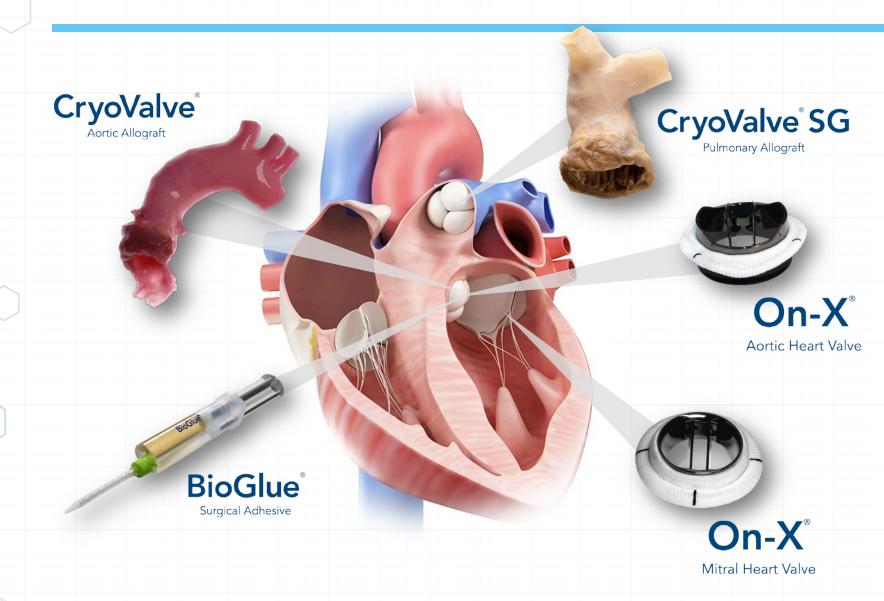




### Forward Looking Statement

Statements made in this presentation that look forward in time or that express management's beliefs, expectations, or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements reflect the views of management at the time such statements are made. These statements include those regarding the ability of our product portfolio to drive growth; the expected growth of the market for our aortic heart valves due to demographics and device adoption; our expectations that our 2016 revenue and gross margins for BioGlue sales in France will improve from 2014 as a result of our move to a direct sales model in France; our expectation that there will be additional upside for our product sales in France as we leverage direct sales of our full product portfolio in France; our ability to expand our sales of BioGlue in Japan as a result of receiving in 2015 an expanded indication for BioGlue for use in thoracic aneurysm, Bentall & LVAD procedures; our expectations regarding our ability to execute on our clinical trial for BioGlue in China and the timeline for that clinical trial; our expectations regarding the ability of the On-X transaction to enhance our growth profile, increase opportunities for cross selling, drive margin expansion, provide CryoLife with a new addressable market opportunity of \$220MM, generate highly attractive margins, facilitate increased adoption of On-X portfolio penetration, enhance and leverage our existing direct sales organization, and strengthen our strategic focus on aortic and mitral valve repair and replacement surgery; the ability of the INR indication for the On-X valve of 1.5 to 2.0, to be a significant differentiator, distinct competitive advantage and catalyst for us to achieve market leadership in the mechanical heart valve market; our belief that compelling clinical data regarding the On-X valve supports future growth; our belief regarding the ability to increase physician familiarity with the On-X heart valve and increase the percent of hospitals stocking the On-X heart valve; and our belief in our ability to increase revenues through differentiated products such as PhotoFix. These forward-looking statements are subject to a number of risks, uncertainties, estimates, and assumptions that may cause actual results to differ materially from current expectations. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for the year ended December 31, 2015 and our subsequent filings with the SEC. CryoLife does not undertake to update its forwardlooking statements.

### **Cardiovascular Technology Business**





### **CryoLife Major Product Lines**





### **Investment Rationale**

Established Product Portfolio Driving Profitable Growth

On-X Acquisition Accelerates Growth and Margin Expansion

Highly Experienced Direct Sales Organization

Proven Leadership

Active Business Development Program



### **Growing Annual Revenues**

CAGR '10-'15: 4.7%

#### Mix Shift to Higher Margin Medical Device Products



Product CAGR '10-'15 8.1%

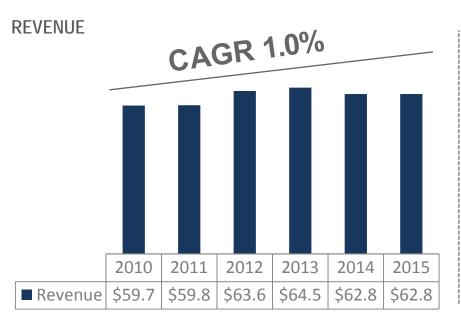
Tissue CAGR '10-'15 1.0%

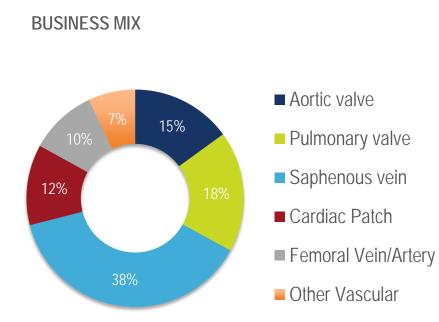
<sup>6</sup> 



### CryoLife Products- Cryopreserved Tissue

#### **Cryopreserved Tissue**: Five-Year Tissue Revenue





#### **PRODUCTS**









Cardiac patch

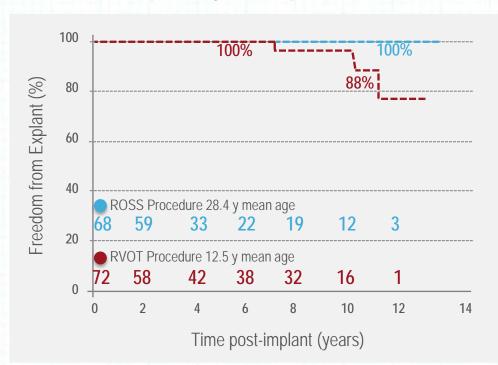
### **Pulmonary Valve Homografts**



#### CryoValve® SG Pulmonary Valves

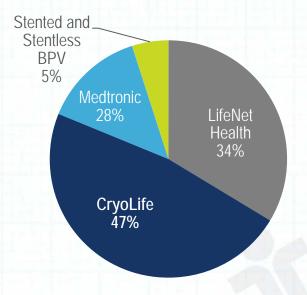
#### SynerGraft® decellularized technology

- + Seven published papers with >2,000 patient years follow up
- + 10 year actuarial freedom from explant = 93%<sup>1</sup>
- + Over 28,000 pulmonary valves implanted since 1984<sup>2</sup>



### US Pulmonary Valve Replacement Market: 2,300 procedures

Market Size = \$24M 2% CAGR



### **Aortic Valve Homografts**

#### CryoValve® Aortic Heart Valves

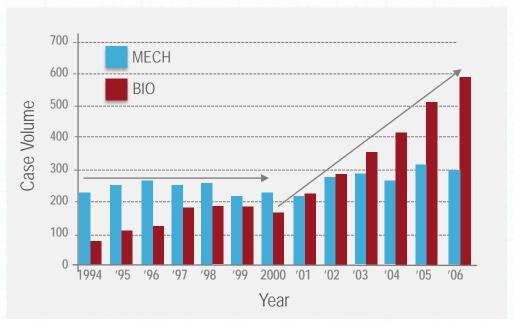




#### Society of Thoracic Surgeons recommendation<sup>1</sup>

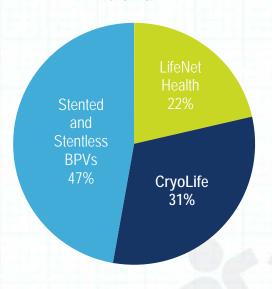
Class I - Homograft replacement of the aortic root should be considered for patients with extensive active endocarditic destruction of the aortic annulus. (Level of evidence B) Class IIa - Homograft replacement of the aortic valve can be considered for patients with endocarditis without annular destruction, especially when the potential for reinfection is elevated. (Level of evidence B)

95% freedom from recurrent endocarditis at 10 years<sup>2,3</sup> Growing market due to demographics and device adoption (TAVR)



### US Aortic Valve Replacement due to Endocarditis Market<sup>5</sup>: 3,200 procedures

Market Size = \$22.5M 9% CAGR



US Incidence of Endocarditis4

1. Svensson LG, et al. Ann Thorac Surg 2013; 95:1491-1505; 2. Doty JR, et al. J Thorac Surg 1998; 115:371-380; 3 Sabik JF, et al. Ann Thorac Surg 2002; 74:650-659; 4. Byrne JG, et al. Ann Thorac Surg 2011;91:2012-2019; 5 Estimated number of endocarditis cases based on figures from "Infective Endocarditis in the U.S., 1998-2009: A Nationwide Study" by Bor DH, et al. PLoS ONE, published 3/20/2013 and Cleveland Clinic estimates that ~30% of diagnosed infective endocarditis require surgery, of those, the majority are aortic (vs mitral or pulmonary) valve."

Note: Market procedures charge and CACD are approximate approach to pulmonary and procedures and procedure

### Saphenous Vein Homografts



#### CryoVein® Saphenous Vein

High limb salvage rates: 70% at 4 years<sup>2</sup>

Excellent resistance to infection<sup>6</sup>

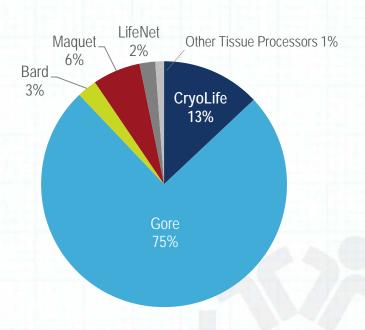
Provides natural suturability and compliance<sup>3</sup>

#### Clinical Effectiveness

Reported Limb Salvage Rates for CryoVein Used in Peripheral Bypass											
Author	n	% redo	1 yr	2 yr	3 yr	4 yr					
Randon, et al <sup>1</sup>	92	62%	85%	77%	70%	NR					
CryoLife Multicenter <sup>2</sup>	381	59%	73%	72%	70%	70%					
Martin, et al <sup>3</sup>	82	94%	84%	81%	NR	62%					
Farber, et al <sup>4</sup>	177	50%	80%	71%	NR	NR					
Buckley, et al <sup>5</sup>	24	27%	80%	80%	NR	NR					

### US Below the Knee Bypass Market: 22,000 procedures (BTK)

Market Size = \$182.5M 1.4% CAGR



<sup>1.</sup> Randon C, et al. J Vasc Surg 2010;51:869-77; 2. CryoLife data on file (ML0041); 3. Martin R, et al. Ann Surg 1994;219;6:664-72; 4. Farber A, et al. J Vasc Surg 2003;38:15-21; 5. Buckley C, et al. J Vasc Surg 2000;32:731-8; 6. Fujitani, et al. J Vasc Surg 1992;15-519-25.



### CryoLife Products- BioGlue Sealant

#### **BioGlue Surgical Sealant**

# **REVENUE CAGR 4.5%**

2012

\$53.0





#### **BioGlue Indications**

Revenue



2010

\$47.3

2011

\$49.3



2013

\$57.6

2014

\$61.7



2015





### Global Expansion- Direct in France

#### Direct in France

- Nominal revenue from France January-September 2015 as distributor sold off inventory
- June 22nd announced agreement with French distributor to take business direct on October 1st, 2015
- 2014 revenue of BioGlue and PerClot was \$3 million
- Expect 2016 revenue and gross margin will improve from 2014 as we sell directly to hospital customers
- Additional upside as we leverage direct sales of the full product portfolio



### Indication Expansion- Japan BioGlue

#### Japan BioGlue

- Current indication only for aortic dissection (5,500 procedures)
- Expanded approval for thoracic aneurysm, Bentall & LVAD (5,500

procedures)

- Doubles existing market from \$5 million to \$10 million
- PMDA approval July 2015
- MHLW reimbursement September 2015





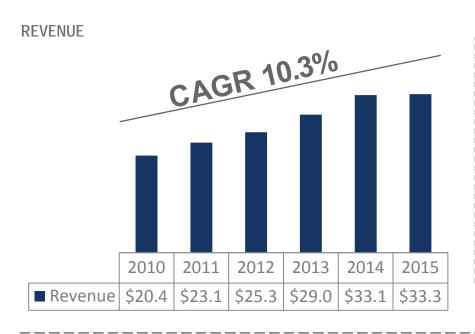
### Global Expansion- BioGlue China

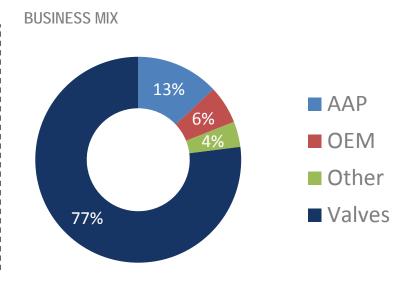
#### BioGlue in China

- Significant market opportunity: >40,000 aortic surgeries
- Estimated Timeline
  - Clinical trial design developed in 2015
  - Standards testing completed, clinical trial approval by CFDA, and Ethics Committee submissions/approvals in 2016
  - Enroll trial and collect follow-up in 2017 (3 month follow-up)
  - 1 year CFDA approval in 2018



### CryoLife Products - On-X Valves





#### **PRODUCTS**



On-X Aortic Valve



On-X Mitral Valve



On-X Ascending Aortic Prosthesis (AAP)



OEM

**15** 







### Transformational acquisition that enhances our growth profile, increases opportunities for cross-selling and drives margin expansion

- » Provides CryoLife with new addressable market opportunity of ~\$220MM
- » Acquired products generate highly attractive margins
- » Facilitates increased adoption of On-X portfolio penetration
- » Enhances and leverages existing CryoLife direct sales organization
- » Strengthens our strategic focus on aortic and mitral valve repair and replacement surgery

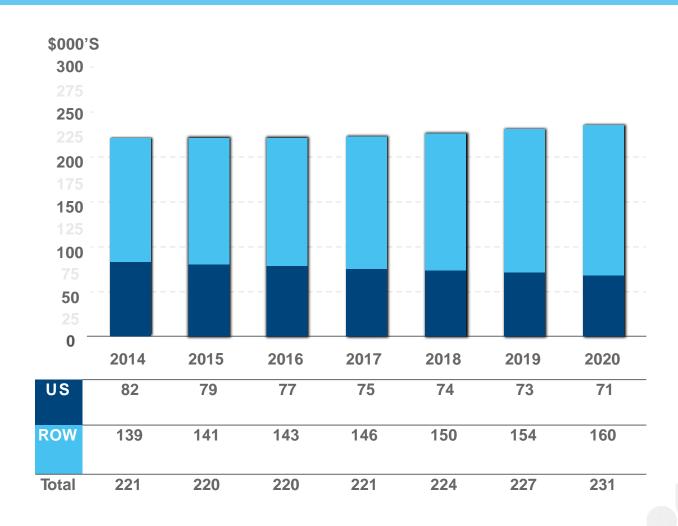
### The combination of On-X best-in-class mechanical valve technology supported by extensive clinical data are key growth drivers

On-X has the **only** FDA approved mechanical aortic valve labeled for an INR of just 1.5 to 2.0, substantially reducing a patient's bleeding risk - a significant differentiator and distinct competitive advantage





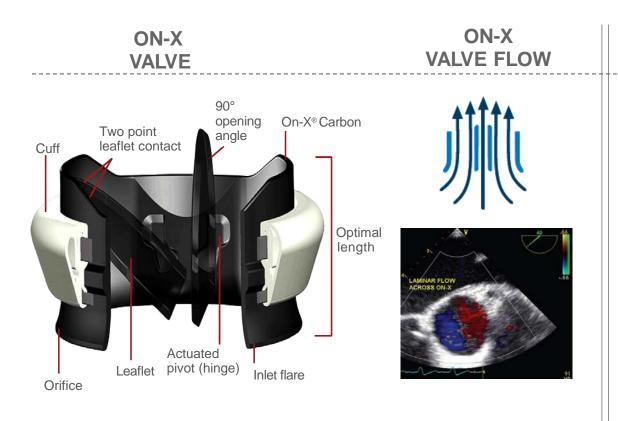
### Worldwide Mechanical Valve Market





### Best-in-Class Mechanical Valve Technology

#### Aortic Valve Flow Comparison



### TRADITIONAL MECHANICAL VALVE FLOW



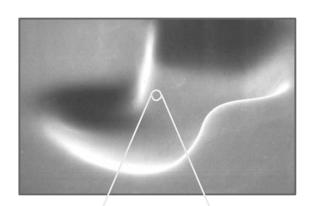


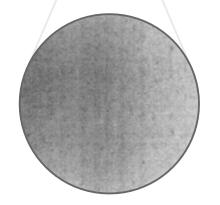


### Best-in-Class Mechanical Valve Technology

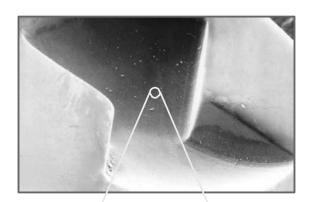
#### Microstructure Comparison

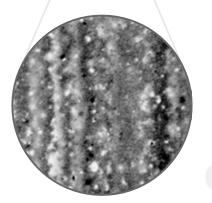
ON-X VALVE
Silicon-free On-X® carbon





#### MARKET-LEADING COMPETITOR



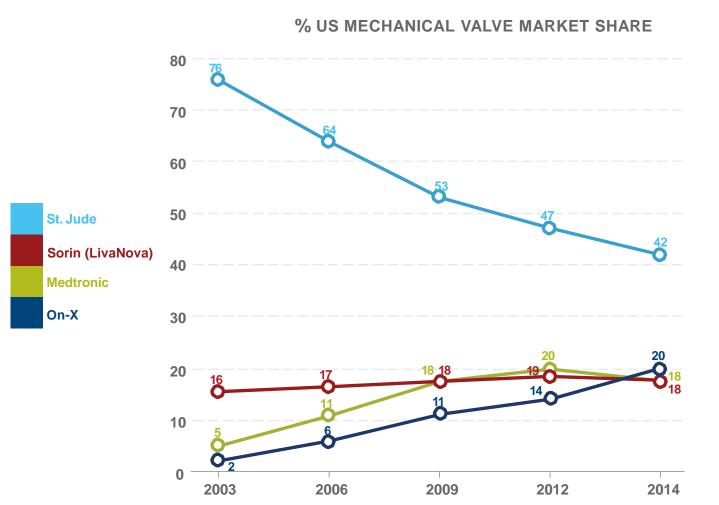






### Steady Growth With Modest Sales Support

#### The Power of On-X Technology







### Significant Recent Developments

PROACT trial results and recent FDA approval of 1.5 to 2.0 INR are catalysts for On-X valve to achieve market leadership

3 Month Randomized

425
Aortic Valve
Replacement
(AVR)
Patients Enrolled

50 Patients Excluded

Patients 2.0-3.0 INR 81 mg Aspirin/day 185 High Risk
AVR Patients
1.5-2.0 INR
81 mg Aspirin/day

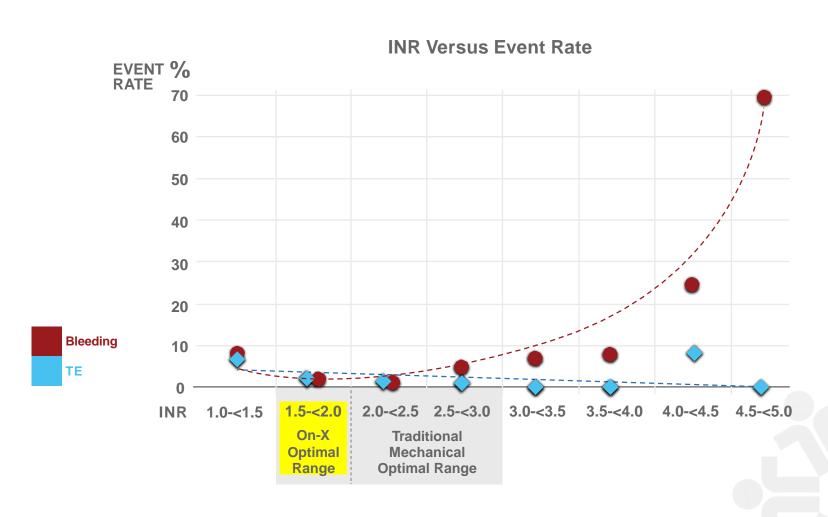
190 Control
AVR Patients
2.0-3.0 INR
81 mg Aspirin/day





### Clinical Data Supports Future Growth

#### Data shows an opportunity to switch future patients from tissue







### Clinical Data Supports Future Growth

On-X has the only FDA approved mechanical aortic valve requiring an INR of just 1.5 to 2.0, substantially reducing a patient's bleeding risk — a significant differentiator and distinct competitive advantage

65%
Reduction in bleeding

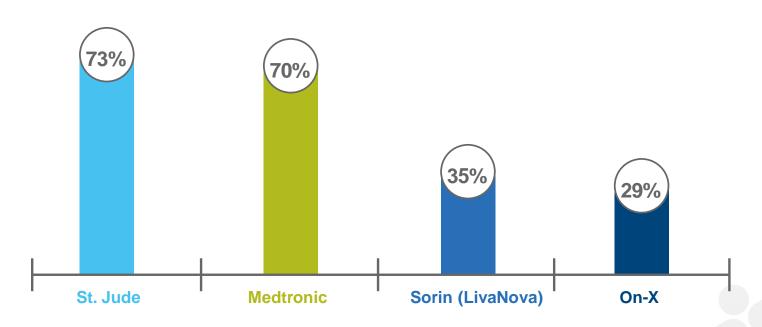
	<b>CONTROL</b> (ptyr=878.6) (2.0-3.0)		<b>TEST</b> (ptyr=766.2) (1.5-2.0)		RATE RATIO	95% CI	P-VALUE
EVENT	N	RATE (%/ptyr)	N	RATE (%/ptyr)	(test/control)		
Major Bleed	34	3.87	12	1.57	0.40	0.21-0.78	0.007
Cerebral Bleed	4	0.46	1	0.13	0.29	0.03-2.56	0.264
Minor Bleed	35	3.98	9	1.17	0.29	0.14-0.61	0.001
Total Bleed	69	7.85	21	2.74	0.35	0.21-1.57	<0.001
Ischemic Stroke	7	0.80	6	0.78	0.98	0.33-2.92	0.975
TIA	7	0.80	11	1.44	1.80	0.70-4.65	0.223
Neurologic Event	14	1.59	17	2.22	1.39	0.69-2.82	0.359
Peripheral TE	1	0.11	4	0.52	4.59	0.51-41.04	0.173
Thrombosis	2	0.23	2	0.26	1.15	0.16-8.14	0.891
Major Bleed, TE, Thrombosis (AATS Guideline)	51	5.80	35	4.57	0.79	0.51-1.21	0.275
Primary Endpoint	86	9.79	44	5.74	0.59	0.41-0.84	0.004
Sudden Death	3	0.34	3	0.39	1.15	0.23-5.68	0.867
Valve-related Death	3	0.34	2	0.26	0.76	0.13-4.57	0.769
Total Mortality	16	1.82	12	1.57	0.86	0.41-1.82	0.693

# Familiarity With Replacement Valve Manufacturers





### **Unaided Awareness**Total 120 | Base: all cardiac surgeons



Q11,12: Please list all of the aortic valve replacement manufacturers you are aware of. Please rate how familiar you are with the following aortic valve replacement manufacturers. Survey conducted April 2015

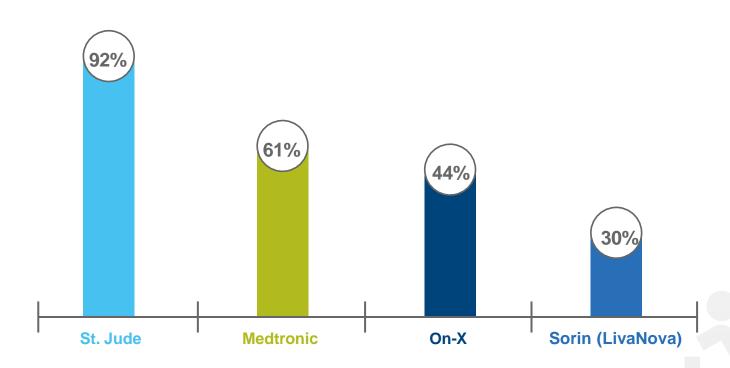
Base: All cardiac surgeons

## Percentage of Hospitals Stocking Each Manufacturer





### Mechanical Aortic Replacement Valves Total 120 | Base: all cardiac surgeons



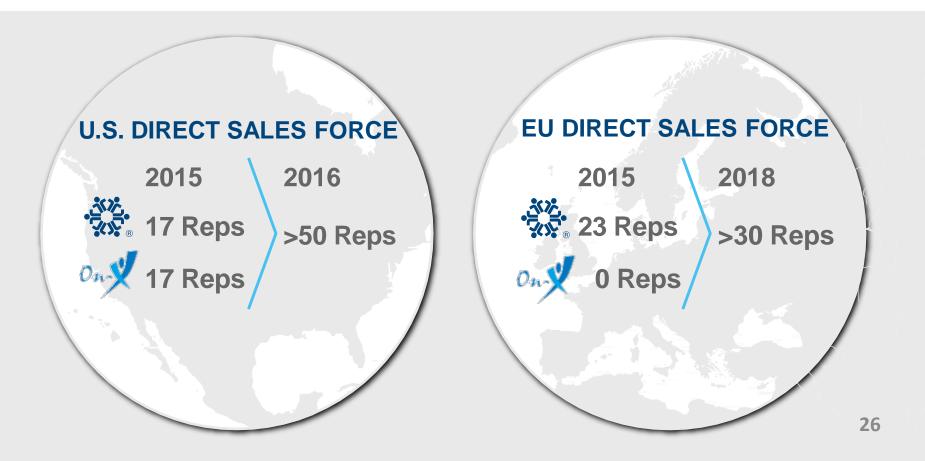
Q13: Does your hospital stock this manufacturer's aortic replacement valve? Survey conducted April 2015
Base: All cardiac surgeons

## **Broadened Direct Sales** and Global Distribution





Combination will create critical mass in global distribution channels with significant opportunities for cross-selling



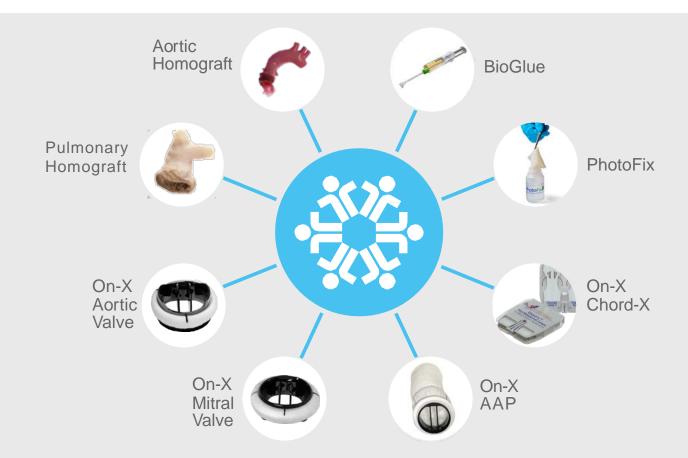


# Strategic Focus on Aortic and Mitral Valve Surgery





Combination of CryoLife and On-X creates a highly differentiated product portfolio with a strategic focus on aortic and mitral valve repair and replacement surgery



### Recent Additions to Leadership Team



PAT MACKIN, Chairman, President & Chief Executive Officer

20 + Years Experience

Previous Companies: Medtronic, Genzyme, Deknatel/Snowden-Pencer

Education: B.S. United States Military Academy at West Point and M.B.A. Kellogg Graduate School of Management

at Northwestern University



JEAN HOLLOWAY, Senior Vice President, General Counsel & Corporate Secretary

30 + Years Experience

Previous Companies: C.R Bard, Medtronic, Boston Scientific, Guidant Corporation

Education: J.D./M.B.A. (cum laude) from the University of Chicago, and two undergraduate degrees from Yale University



JOHN DAVIS, Senior Vice President, Global Sales & Marketing

25 + Years Experience

**Previous Companies:** CorMatrix Cardiovascular, St. Jude, Medtronic **Education:** Bachelor of Arts, English from Western Carolina University



BILL MATTHEWS, Senior Vice President, Operations, Quality and Regulatory

30 + Years Experience

**Previous Companies:** BioDevice Solutions, Fresenius Medical Care, Cardinal Health's Viasys Healthcare, Beiersdorf AG **Education:** Bachelor of Science in Chemistry from St. Peter's University and Business Administration programs from

Rutgers University and Fairleigh Dickson University





### Active Business Development Program

- ✓ Physician preference products
- ✓ Higher growth rate than CRY
- ✓ Higher margin than CRY
- ✓ Competitive advantage in market
- ✓ Synergistic to CRY



### Summary

Established Product Portfolio Driving Profitable Growth

Proven Leadership

New Growth Opportunities Should Drive Top Line and Margin Expansion

Leverage our Strong Direct Sales and Distribution Platform

Solid Financial Position

**Active Business Development Program** 



## www.cryolife.com



