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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
Date of Report (Date of earliest event reported): February 15, 2016

CRYOLIFE, INC.  
(Exact name of registrant as specified in its charter)

Florida  
(State or Other Jurisdiction  
of Incorporation)

1-13165  
(Commission File Number)

59-2417093  
(IRS Employer  
Identification No.)

1655 Roberts Boulevard, N.W., Kennesaw, Georgia 30144  
(Address of principal executive office) (zip code)  
Registrant's telephone number, including area code: (770) 419-3355

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

**Item 7.01 Regulation FD Disclosure.**

CryoLife, Inc. (the “Company”) is furnishing the presentation slides attached as Exhibit 99.1 to this Current Report, which the Company will present at meeting of Atlanta Unlimited Investments LLC on February 15, 2016 and may from time to time use in other conferences or conversations with investors and analysts. This presentation will also be posted on the investor relations portion of the Company’s website, [www.cryolife.com](http://www.cryolife.com), during the time period when it is used by the Company.

The information furnished in this Current Report and the exhibit attached hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<b>Exhibit No.</b>	<b>Description</b>
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99.1*	CryoLife, Inc. Investor Presentation, dated February 15, 2016
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\* Furnished herewith, not filed.

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**Pat Mackin**  
**President & CEO**  
**February 15, 2016**



# 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 CryoLife's ability to become a leader in providing unique and differentiated technologies and solutions for patients with structural heart disease that will improve clinical outcomes as well as reduce overall cost to the healthcare system; the ability of our product portfolio to drive growth; the ability of the On-X acquisition to accelerate growth and expand gross margins; 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; our belief in our ability to increase revenues through differentiated products such as PhotoFix; our expectations regarding our ability to execute on the PerClot clinical trial and our belief that we can obtain PMA approval for PerClot in the US by 2019; the anticipated benefits for our business development program, including double digit CAGR in adjusted non-GAAP earnings from 2016 – 2020; and our beliefs regarding our expectations for financial performance in 2016. 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, 2014 and our subsequent filings with the SEC, including our Form 10-K for year ended December 31, 2015. CryoLife does not undertake to update its forward-looking statements.

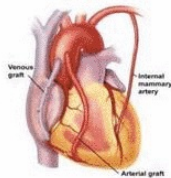


# My Background (1988-2015)

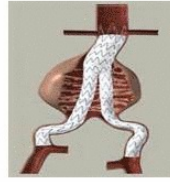
1988-1991



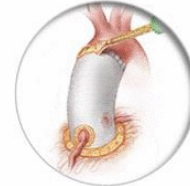
1991-2002



2002-2014



2014-Present



3



# CryoLife- Cardiovascular Technology Business



**CryoValve<sup>®</sup>**  
Aortic Allograft

**CryoValve<sup>®</sup> SG**  
Pulmonary Allograft

**BioGlue<sup>®</sup>**  
Surgical Adhesive

**On-X<sup>®</sup>**  
Heart Valve

4



## CryoLife Vision Slide

*Become a leader in providing unique and differentiated technologies and solutions for patients with structural heart disease that will improve clinical outcomes as well as reduce the overall cost to the healthcare system*







# Investment Rationale

Proven Leadership

Established Product Portfolio Driving Profitable Growth

On-X Acquisition Accelerates Growth and Margin Expansion

Highly Experienced Direct Sales Organization

Active Business Development Program



# 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





# Growing Annual Revenues

CAGR '10-'15: 4.7%

Mix Shift to Higher Margin Medical Device Products



\*Excludes grant revenue





# CryoLife Major Product Lines

## Allograft Tissues



37% of Revenue

## On-X Heart Valve



20% of Revenue

## BioGlue<sup>®</sup> Surgical Adhesive



35% of Revenue

Source: Revenue calculated as pro forma 2015



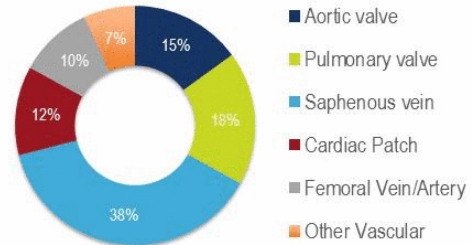
# CryoLife Products- Cryopreserved Tissue

## Cryopreserved Tissue: Five-Year Tissue Revenue

### REVENUE



### BUSINESS MIX



### PRODUCTS



Pulmonary valve



Aortic valve



Saphenous vein



Cardiac patch

# Pulmonary Valve Homografts

CryoValve® SG Pulmonary Valves

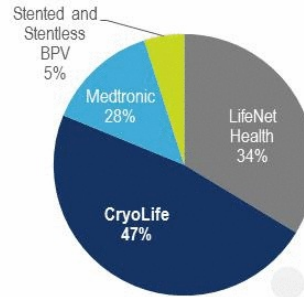
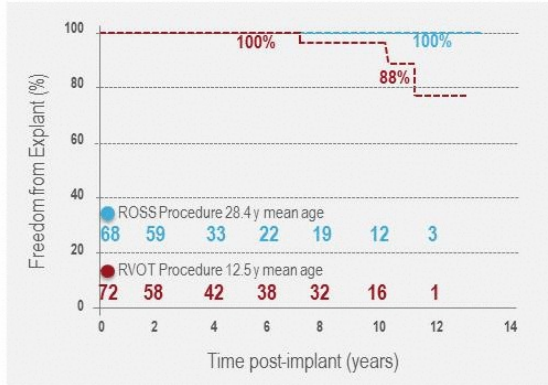


## SynerGraft® decellularized technology

- + 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



<sup>1</sup> US Clinical Effectiveness<sup>1</sup>

<sup>2</sup> CryoLife, Inc. Postclearance Study (C9G801.002), data on file; 2. CryoLife, Inc. data on file

Note: Market procedures, share, size, and CAGR are approximate annual U.S. numbers based on actual CryoLife data and market reports, including LSI, Idata and IMS.

# 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)

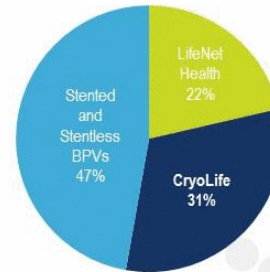
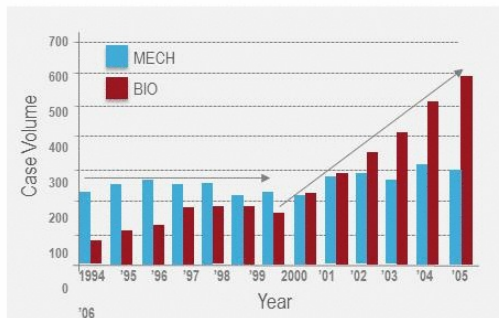
95% freedom from recurrent endocarditis at 10 years<sup>2,3</sup>

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 Endocarditis<sup>4</sup>

1. Svensson LG, et al. Ann Thorac Surg 2013; 96:1491-1505. 2. Doty JR, et al. J Thorac Surg 1996; 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., 1996-2009: A Nationwide Study" by Bor DJ, et al. PLoS ONE, published 0/20/2013 and Cleveland Clinic estimates that ~30% of diagnosed infective endocarditis require surgery, of those, the majority are aortic (vs mitral or pulmonary) valve.<sup>6</sup>

Note: Market procedures, share, size, and CAGR are approximate annual U.S. numbers based on actual CryoLife data, clinical publications, and market reports, including LSI, Data and IMS.



# CryoLife Products- BioGlue Sealant

## BioGlue Surgical Sealant

### REVENUE



### BioGlue Indications







# Global Expansion- Direct in France

## Direct in France

- No 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

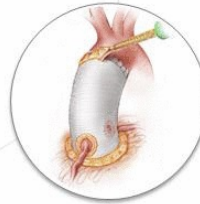




# Indication Expansion- Japan BioGlue

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

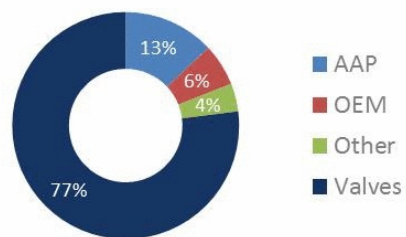


# CryoLife Products - On-X Valves

## REVENUE



## BUSINESS MIX



## PRODUCTS



On-X Aortic Valve



On-X Mitral Valve



On-X Ascending Aortic Prosthesis (AAP)



OEM



**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

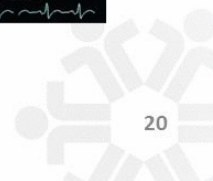
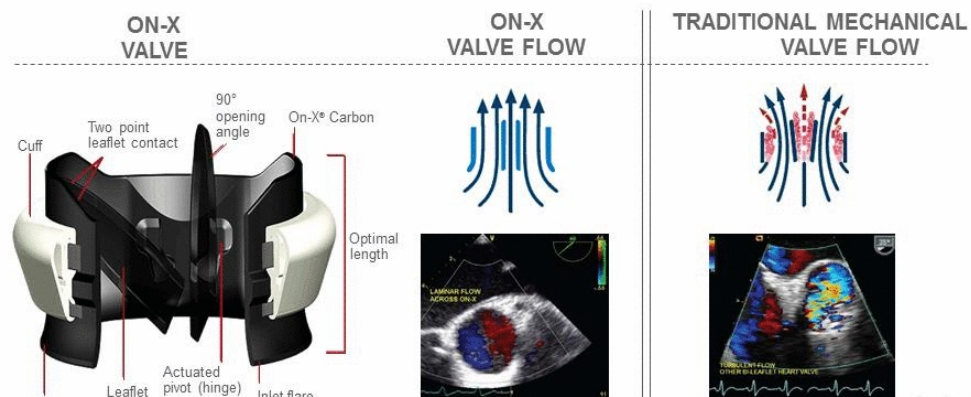


Source: Millennium Research Group



# Best-in-Class Mechanical Valve Technology

## Aortic Valve Flow Comparison

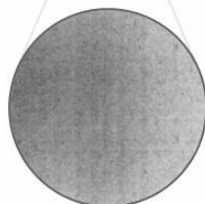
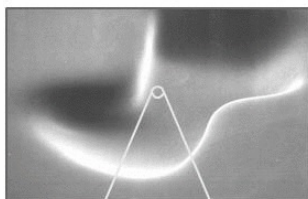


# Best-in-Class Mechanical Valve Technology

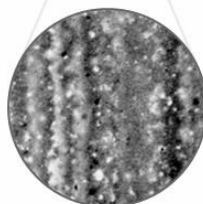
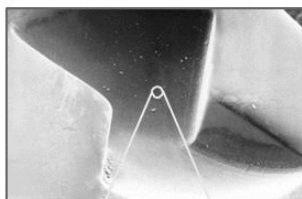
## Microstructure Comparison

### ON-X VALVE

Silicon-free On-X® carbon



### MARKET-LEADING COMPETITOR

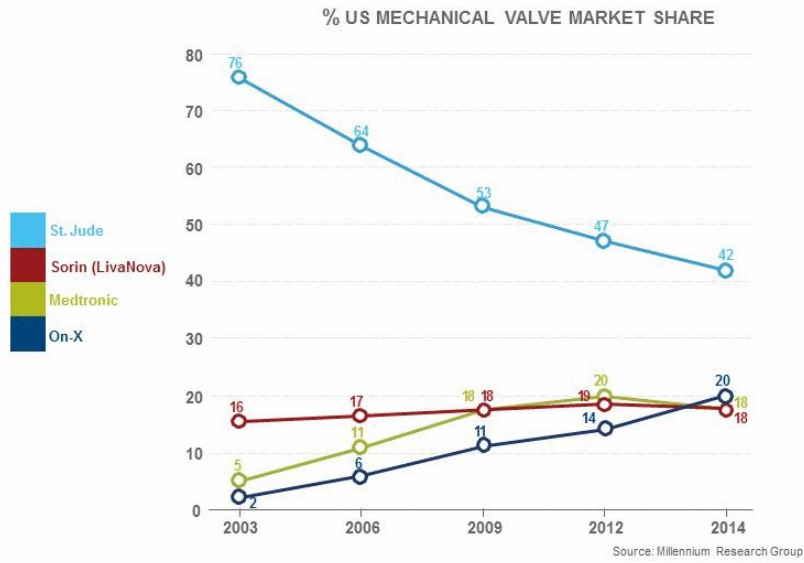






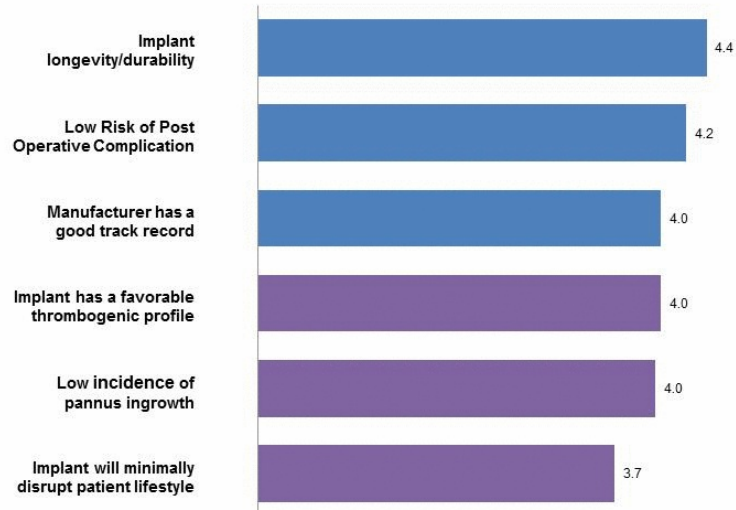
# Steady Growth With Modest Sales Support

The Power of On-X Technology





## Surgeon Prioritized Criteria for Selecting Valves





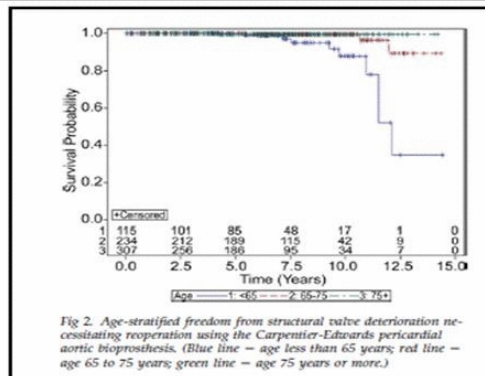
# Late Outcomes with Tissue Valves Vary by Age

Patients <65 years old start to receive explants at year 7 and 70% are explanted by year 12

## Late Outcomes for Aortic Valve Replacement With the Carpentier-Edwards Pericardial Bioprosthesis: Up to 17-Year Follow-Up in 1,000 Patients

R. Scott McClure, MD, SM, Narendren Narayanasamy, MD, Esther Wiegerinck, BA, Stuart Lipsitz, ScD, Ann Maloney, BA, John G. Byrne, MD, Sary F. Aranki, MD, Gregory S. Couper, MD, and Lawrence H. Cohn, MD

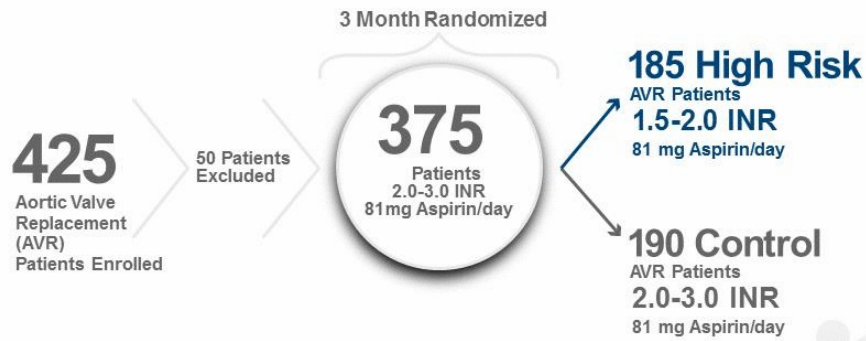
Division of Cardiac Surgery, Brigham and Women's Hospital, and Center for Surgery and Public Health, Harvard Medical School, Boston, Massachusetts





# 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

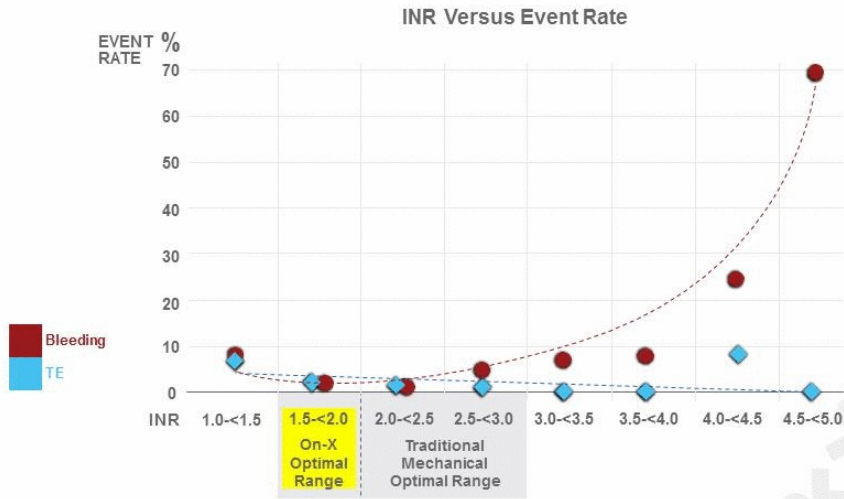


Source: PMA P000037 supplement 30, approval date April 01, 2015



# Clinical Data Supports Future Growth

Data shows an opportunity to switch future patients from tissue



Source: Puskas et al., J Thorac Cardiovasc Surg 2014;147:1202-11





# 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

EVENT	CONTROL (ptyr=878.6) (2.0-3.0)		TEST (ptyr=766.2) (1.5-2.0)		RATE RATIO (test/control)	95% CI	P-VALUE
	N	RATE (%/ptyr)	N	RATE (%/ptyr)			
<b>Major Bleed</b>	<b>34</b>	<b>3.87</b>	<b>12</b>	<b>1.57</b>	<b>0.40</b>	<b>0.21-0.78</b>	<b>0.007</b>
Cerebral Bleed	4	0.46	1	0.13	0.29	0.03-2.56	0.264
<b>Minor Bleed</b>	<b>35</b>	<b>3.98</b>	<b>9</b>	<b>1.17</b>	<b>0.29</b>	<b>0.14-0.61</b>	<b>0.001</b>
<b>Total Bleed</b>	<b>69</b>	<b>7.85</b>	<b>21</b>	<b>2.74</b>	<b>0.35</b>	<b>0.21-1.57</b>	<b>&lt;0.001</b>
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
<b>Primary Endpoint</b>	<b>86</b>	<b>9.79</b>	<b>44</b>	<b>5.74</b>	<b>0.59</b>	<b>0.41-0.84</b>	<b>0.004</b>
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

Source: PMA P000037 supplement 30, approval date April 01, 2015



## Surgeon Question

Do you think the PROACT results showing 65% reduction in bleeding are compelling enough to get surgeons to change from their current mechanical valve to On-X?

83% Responded Yes N=35



Browser tabs: http://www.wsj.com/articles/clot-risk-is-seen-in-some-heart-va... MSN.com - Hotmail, O... CryoLife, Providing Stat... CNN - Breaking News... WSJ Clot Risk Is Seen in S... X

File Edit View Favorites Tools Help

DOW JONES, A NEWS CORP COMPANY

DIA Futures ▲ 15772 1026P 500 F ▲ 1846.25 119% Stock 600 ▲ 309.45 197% US 10 Yr ▲ -9/32 Yield 1.692% Crude Oil ▼ 27.60 5.30% Euro ▲ 1.1280 -0.39%

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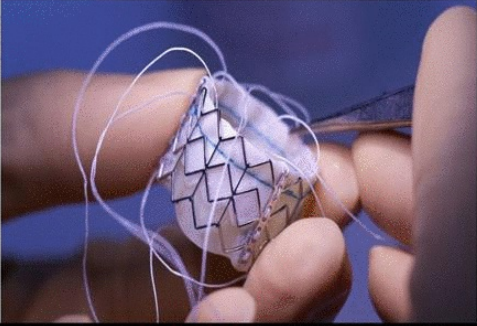
◀ Citizens, Sanders Clash Over Cost of Plans ▶ Gravitational Waves Detected, Verifying Part of Einstein Theory ▶ Veterans' Wait After Trump Fundraiser Shows Hurdles... ▶ Oregon Standoff Ends as Last 4 Occupiers Surrender ▶ Min. Chapo's Breach

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U.S. | GENERAL NEWS

## Clot Risk Is Seen in Some Heart Valves

The FDA and cardiologists warn about animal tissue devices that have been widely used for decades



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7:03 AM 7/12/2016





## Surgeon Question

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The FDA said the findings, in studies published online Monday by the New England Journal of Medicine, “have raised important questions about bioprosthetic aortic valves.” Evidence suggests minuscule clots on the valves “may cause restricted motion,” the agency said in a safety advisory. - WSJ October 5, 2015

Do you think this is a real is a real issue?

54% Answered Yes N=39





# Meta Analysis Mechanical vs. Bioprosthetic Valves

## Mechanical Versus Bioprosthetic Aortic Valve Replacement in Patients Aged 40 to 70 Years: A Systematic Review and Meta-Analysis

James J. Wu, BMusStudies, Michael Seco, BMedSc, MBBS,  
James B. Edelman, MBBS(Hons), PhD, Guy D. Eslick, DrPH, PhD,  
Michael K. Wilson, MBBS, FRACS, Michael P. Vallely, MBBS, PhD,  
Michael J. Byrom, MBChB, PhD, and Paul G. Bannon, MBBS, PhD

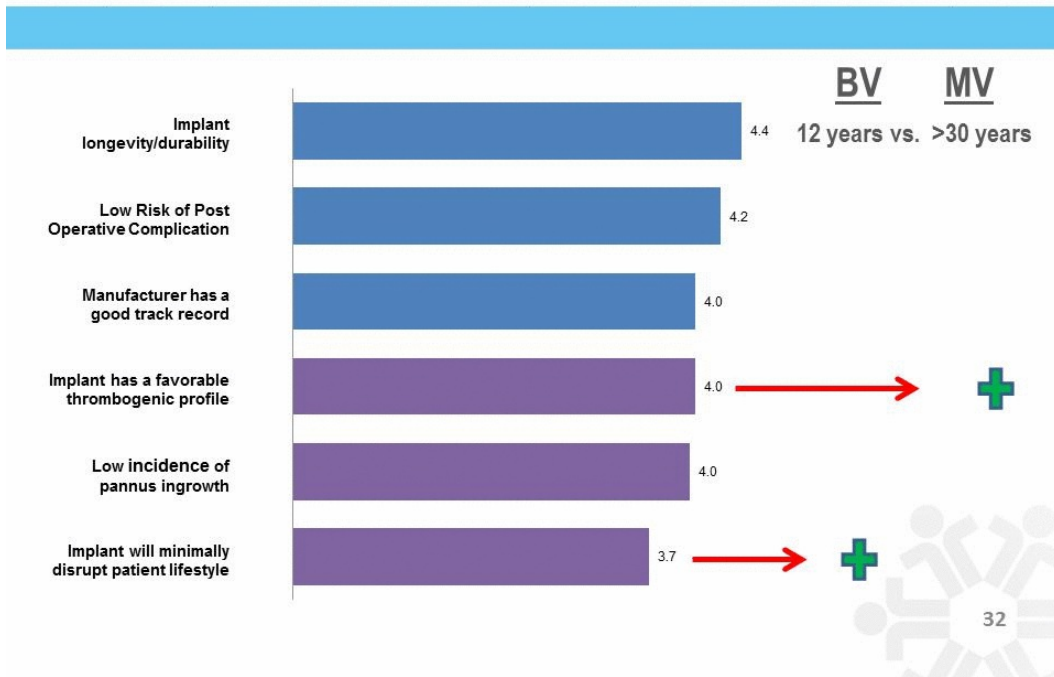
Sydney Medical School, University of Sydney, Sydney; Baird Institute of Applied Heart and Lung Surgical Research, Sydney;  
Cardiothoracic Surgery Unit and Institute of Academic Surgery, Royal Prince Alfred Hospital, Sydney; Australian School of Advanced  
Medicine, Macquarie University, Sydney; and Whiteley-Martin Research Centre, Sydney, Australia

Review of 893 Studies  
13 Selected for Analysis  
4,287 Mechanical Valves vs. 4,259 Bioprosthetic Valves





## Surgeon Prioritized Criteria for Selecting Valve





## Surgeon Question

Do the previously shown results of the Meta analysis prioritized by physician attributes ranking change the current paradigm in favor of On-X vs. tissue valves in patients <65?

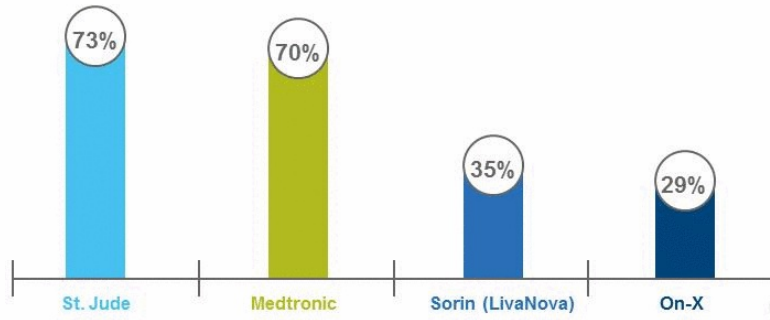
56% Answered Yes N=39



# + Familiarity With Replacement Valve Manufacturers



Unaided Awareness  
Total 120 | Base: all cardiac surgeons



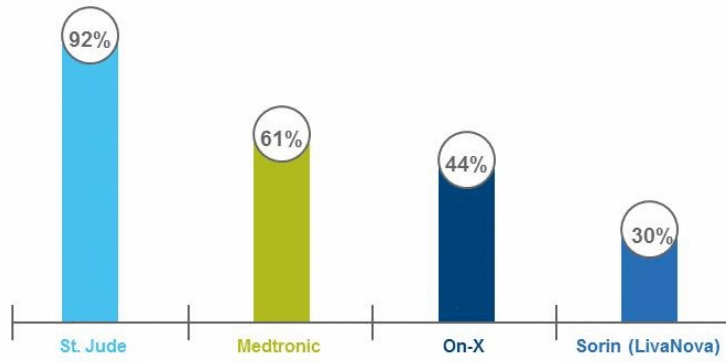
Q11.12: Please list all of the aortic valve replacement manufacturers you are aware of.  
Please rate how familiar you are with the following aortic valve replacement manufacturers.  
Survey conducted April 2015  
Base: All cardiac surgeons



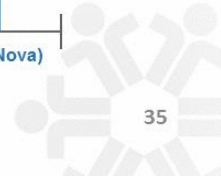
# + Percentage of Hospitals Stocking Each Manufacturer



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



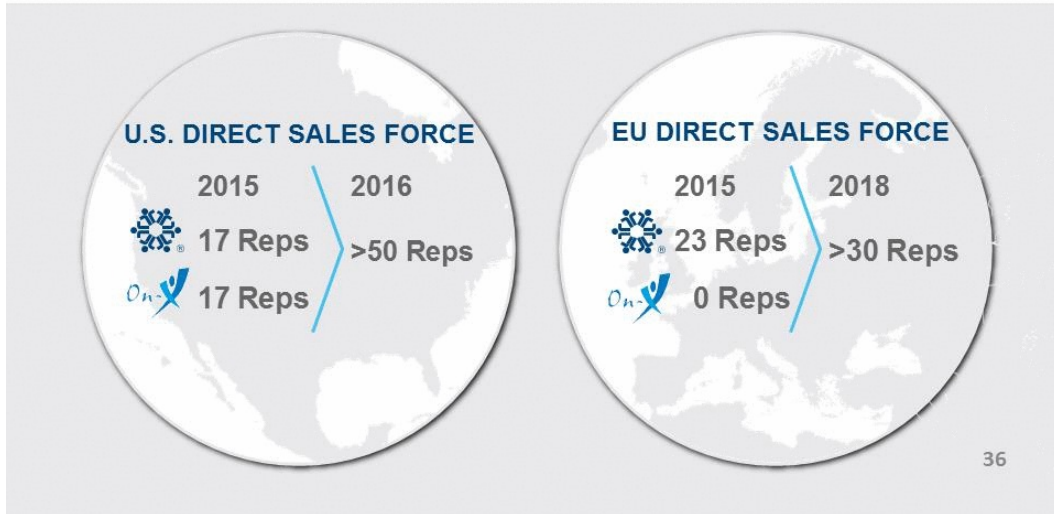
Q13: Does your hospital stock this manufacturer's aortic replacement valve?  
Survey conducted April 2015  
Base: All cardiac surgeons



## + Broadened Direct Sales and Global Distribution



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



# New Products

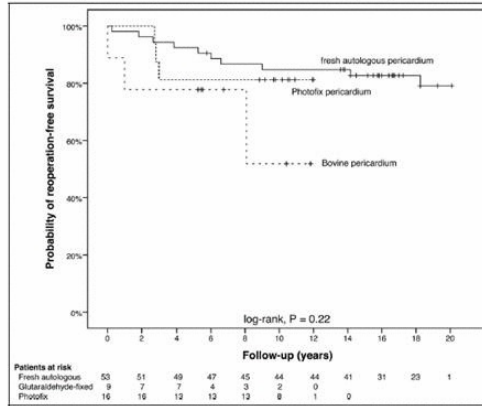


## PhotoFix™ Decellularized Bovine Pericardium

Novel photofixation process promotes crosslinking of internal collagen structure

Only truly glutaraldehyde-free bovine pericardial patch

Handling characteristics similar to autologous pericardium



Clinical Effectiveness<sup>1</sup>

1. Kalangos et al., W Journal for Ped and Congen Heart Surgery (2013)

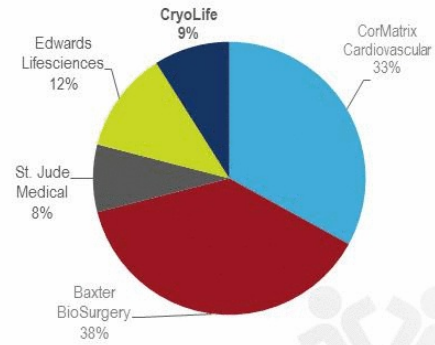
Note: Market procedures, share, size, and CAGR are approximate annual U.S. numbers based on actual CryoLife data and market reports, including LSI, iData and IMS.

US Patch Market:

19,500 procedures

Market Size = \$18M

11% CAGR

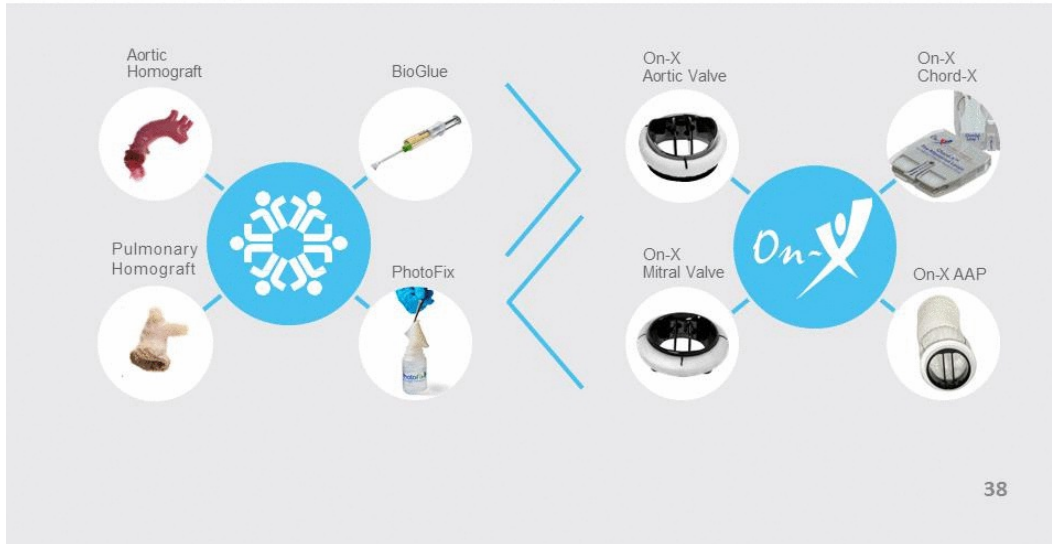






# Enhanced Cross-selling Opportunities

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





# Indication Expansion

## PerClot® US IDE Trial

- **Adjunct hemostatic device to control capillary, venular, and arteriolar bleeding**
- **Methods**
  - + Prospective, multicenter, randomized, controlled vs. Bard Arista™
  - + Non-inferior hemostasis at 7 minutes
  - + Bleeding assessed using an objective, validated model
  - + 324 eligible subjects across 15 centers
    - Cardiac, General, and Urological
    - 108 patients per arm
    - 3 month follow-up for most procedures
- **Goal is to complete enrollment in 2016 or 2017 and FDA approval in 2019**



Bruckner B. and Loebe M. (2012)



## Active Business Development Program



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





## Anticipated Financial Benefits

- Acceleration of revenue growth through acquired products, channel expansion and cross-selling opportunities
- On-X product portfolio revenues projected to grow at double digit CAGR from 2016 – 2020
- Gross margin expansion
- Double digit CAGR in adjusted non-GAAP earnings from 2016 – 2020
- Future opportunities to invest in the operations of the business





# 2016 Guidance Summary



	<b>February 15, 2016</b>
<b>Total Revenues</b>	\$178M- \$180M Mid-single digits % pro-forma increase over 2015
<b>Product revenues</b>	Mid-single digits % pro-forma increase over 2015
<b>Tissue processing revenues</b>	Mid-single digits % increase over 2015
<b>Gross margins</b>	Approximately 63%
<b>R&amp;D expenses</b>	\$13.0M - \$15.0M
<b>Non-GAAP adjusted income per common share</b>	\$0.29 - \$0.32





[www.cryolife.com](http://www.cryolife.com)

 **CryoLife**<sup>®</sup>  
Life Restoring Technologies

