
**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): July 31, 2020

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)

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value	CRY	NYSE

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Section 2 Financial Information.**Item 2.02 Results of Operations and Financial Condition.**

On July 30, 2020, CryoLife, Inc. (“CryoLife” or the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2020. CryoLife hereby incorporates by reference herein the information set forth in its press release dated July 30, 2020, a copy of which is attached hereto as Exhibit 99.1. On July 30 2020, the Registrant held a conference call and web cast with respect to its financial results for the three and six month periods ended June 30, 2020. The conference call script of the Registrant is furnished as exhibit 99.2. Except as otherwise provided in the press release, the press release speaks only as of the date of such press release and it shall not create any implication that the affairs of CryoLife have continued unchanged since such date.

The information provided pursuant to this Item 2.02 is to be considered “furnished” pursuant to Item 2.02 of Form 8-K and shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended, nor shall it be deemed incorporated by reference into any of CryoLife’s reports or filings with the Securities and Exchange Commission, whether made before or after the date hereof, except as expressly set forth by specific reference in such report or filing.

Except for the historical information contained in this report, the statements made by CryoLife are forward-looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. CryoLife’s future financial performance could differ significantly from the expectations of management and from results expressed or implied in the press release. Please refer to the last paragraph of the text portion of the press release for further discussion about forward-looking statements. For further information on risk factors, please refer to “Risk Factors” contained in CryoLife’s most recently filed Form 10-K and its subsequent filings with the Securities and Exchange Commission, as well as in the press release attached as Exhibit 99.1 hereto. CryoLife disclaims any obligation or duty to update or modify these forward-looking statements.

Section 7 Regulation FD.**Item 7.01 Regulation FD Disclosure.**

See "Item 2.02 — Results of Operations and Financial Condition."

This information is not "filed" pursuant to the Securities Exchange Act of 1934 and is not incorporated by reference into any Securities Act of 1933 registration statements. Additionally, the submission of the report on Form 8-K is not an admission of the materiality of any information in this report that is required to be disclosed solely by Regulation FD.

Section 9 Financial Statements and Exhibits.**Item 9.01(d) Exhibits.**

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
99.1 *	Press Release dated July 30, 2020
99.2 *	Conference call script of July 30, 2020

*This exhibit is furnished, not filed.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, CryoLife, Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: July 31, 2020

CRYOLIFE, INC.

By: /s/ D. Ashley Lee
Name: D. Ashley Lee
Title: Executive Vice President, Chief
Operating Officer and Chief
Financial Officer

**FOR IMMEDIATE RELEASE****Contacts:**

CryoLife
D. Ashley Lee
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CryoLife Reports Second Quarter 2020 Financial Results**Second Quarter and Recent Business Highlights:**

- Achieved total revenues of \$53.8 million in the second quarter 2020 versus \$71.1 million in the second quarter of 2019
 - Total revenues decreased 24% and decreased 23% on a non-GAAP constant currency basis versus second quarter 2019
- Completed \$100.0 million convertible debt financing for general corporate purposes, including the repayment of approximately \$30.0 million outstanding under the revolving credit facility
- Initiated enrollment in PROACT Xa clinical trial
- Initiated limited market release of E-vita Open NEO and E-nside and limited relaunch of NEXUS™

ATLANTA, GA – (July 30, 2020) – CryoLife, Inc. (NYSE: CRY), a leading cardiac and vascular surgery company focused on aortic disease, announced today its financial results for the second quarter ended June 30, 2020.

“Despite the disruptions to our business from COVID-19, we posted a solid second quarter and advanced on several of our key initiatives. We believe our business is weathering the pandemic well, as we believe the majority of products in our portfolio are used in procedures that cannot be postponed or delayed for long,” commented Pat Mackin, Chairman, President, and Chief Executive Officer. “We saw an improvement in procedure volumes sequentially month to month from April to June with a corresponding increase in revenue growth over those months. Our manufacturing facilities continue to run at near capacity and our supply chain remains largely intact. We have continued to fund R&D programs related to products that we believe will deliver revenue in 2021 and 2022, including our regulatory approvals for U.S. PerClot PMA, BioGlue China and PROACT Mitral. We initiated limited market releases for Evita Open NEO and E-nside, with E-nya anticipated to follow by October, and a limited relaunch of NEXUS. We also initiated enrollment in our PROACT Xa clinical trial. Lastly, we completed a \$100.0 million convertible debt financing to use for general corporate purposes, including the repayment of our \$30.0 million revolver draw down. We have the financial strength to be opportunistic on the business development front. Given these achievements in the second quarter, we anticipate continued momentum in the second half of 2020 and are optimistic that we will have a strong 2021.”

Second Quarter Financial Results

Total revenues for the second quarter of 2020 were \$53.8 million, reflecting a decrease of (24%), and (23%) on a non-GAAP constant currency basis, both compared to the second quarter of 2019. Decreases in all product lines reflect the impact of the COVID-19 pandemic on the number of procedures using our products.

Net loss for the second quarter of 2020 was (\$3.7) million, or (\$0.10) per fully diluted common share, compared to net income of \$2.8 million, or \$0.07 per fully diluted common share for the second quarter of 2019. Non-GAAP net loss for the second quarter of 2020 was (\$835,000), or (\$0.02) per fully diluted common share, compared to non-GAAP net income of \$4.1 million, or \$0.11 per fully diluted common share for the second quarter of 2019.

2020 Financial Outlook

Due to uncertainties resulting from the COVID-19 pandemic, the Company is not issuing 2020 financial guidance at this time.

All numbers are presented on a GAAP basis except where expressly referenced as non-GAAP. The Company does not provide GAAP income per common share on a forward-looking basis because the Company is unable to predict with reasonable certainty business development and acquisition-related expenses, purchase accounting fair value adjustments, and any unusual gains and losses without unreasonable effort. These items are uncertain, depend on various factors, and could be material to results computed in accordance with GAAP.

The Company's financial performance for 2020 is subject to the risks identified below.

Non-GAAP Financial Measures

This press release contains non-GAAP financial measures. Investors should consider this non-GAAP information in addition to, and not as a substitute for, financial measures prepared in accordance with U.S. GAAP. In addition, this non-GAAP financial information may not be the same as similar measures presented by other companies. The Company's non-GAAP net income and non-GAAP EBITDA results exclude (as applicable) business development and integration expense, severance expense, amortization expense, inventory basis step-up expense, loss on foreign currency revaluation, stock-based compensation expense, and corporate rebranding expense. The Company believes that these non-GAAP presentations provide useful information to investors regarding unusual non-operating transactions; the operating expense structure of the Company's existing and recently acquired operations, without regard to its on-going efforts to acquire additional complementary products and businesses and the transaction and integration expenses incurred in connection with recently acquired and divested product lines; and the operating expense structure excluding fluctuations resulting from foreign currency revaluation and stock-based compensation expense. The Company believes it is useful to exclude certain expenses because such amounts in any specific period may not directly correlate to the underlying performance of its business operations or can vary significantly between periods as a result of factors such as acquisitions, or non-cash expense related to amortization of previously acquired tangible and intangible assets. The Company has excluded the impact of changes in currency exchange from certain revenues to evaluate growth rates on a constant currency basis. The Company does, however, expect to incur similar types of expenses and currency exchange impacts in the future, and this non-GAAP financial information should not be viewed as a statement or indication that these types of expenses will not recur.

Webcast and Conference Call Information

The Company will hold a teleconference call and live webcast later today, July 30, 2020 at 4:30 p.m. ET to discuss the results followed by a question and answer session. To listen to the live teleconference, please dial 201-689-8261. A replay of the teleconference will be available through August 6, 2020 and can be accessed by calling (toll free) 877-660-6853 or 201-612-7415. The Conference ID for the replay is 13706961.

The live webcast and replay can be accessed by going to the Investor Relations section of the CryoLife website at www.cryolife.com and selecting the heading Webcasts & Presentations.

About CryoLife, Inc.

Headquartered in suburban Atlanta, Georgia, CryoLife is a leader in the manufacturing, processing, and distribution of medical devices and implantable tissues used in cardiac and vascular surgical procedures focused on aortic repair. CryoLife markets and sells products in more than 100 countries worldwide. For additional information about CryoLife, visit our website, www.cryolife.com.

Forward Looking Statements

Statements made in this press release 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 our beliefs that our business is weathering the pandemic well; our belief that the majority of products in our portfolio are used in procedures that cannot be postponed or delayed for long; that we are continuing to fund R&D programs for products that will deliver revenue in 2021 and 2022, including our regulatory approvals for U.S. PerClot PMA, BioGlue China and PROACT Mitral; we will relaunch E-nya on a limited basis by October, 2020; we have the financial strength to be opportunistic on the business development front; and we will have continued momentum in the second half of 2020 and a strong 2021. 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, including the continued effects of COVID-19 and government mandates implemented to address the pandemic. These risks and uncertainties include the risk factors detailed in our Securities and Exchange Commission filings, including our Form 10-K for year ended December 31, 2019. CryoLife does not undertake to update its forward-looking statements, whether as a result of new information, future events, or otherwise.

CryoLife, Inc. and Subsidiaries
Financial Highlights
(In thousands, except per share data)

	(Unaudited) Three Months Ended June 30,		(Unaudited) Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Products	\$ 37,268	\$ 51,168	\$ 83,688	\$ 99,569
Preservation services	16,503	19,971	36,512	39,075
Total revenues	53,771	71,139	120,200	138,644
Cost of products and preservation services:				
Products	10,040	14,489	23,080	28,315
Preservation services	7,841	9,684	17,059	19,090
Total cost of products and preservation services	17,881	24,173	40,139	47,405
Gross margin	35,890	46,966	80,061	91,239
Operating expenses:				
General, administrative, and marketing	32,288	34,623	71,290	71,143
Research and development	5,522	5,841	11,878	11,389
Total operating expenses	37,810	40,464	83,168	82,532
Operating (loss) income	(1,920)	6,502	(3,107)	8,707
Interest expense	3,652	3,811	7,040	7,705
Interest income	(66)	(233)	(168)	(349)
Other (income) expense, net	(740)	185	2,922	262
(Loss) income before income taxes	(4,766)	2,739	(12,901)	1,089
Income tax benefit	(1,077)	(93)	(2,547)	(1,446)
Net (loss) income	\$ (3,689)	\$ 2,832	\$ (10,354)	\$ 2,535
(Loss) income per common share:				
Basic	\$ (0.10)	\$ 0.08	\$ (0.27)	\$ 0.07
Diluted	\$ (0.10)	\$ 0.07	\$ (0.27)	\$ 0.07
Weighted-average common shares outstanding:				
Basic	37,520	37,156	37,455	36,968
Diluted	37,520	37,838	37,455	37,789
Net (loss) income	\$ (3,689)	\$ 2,832	\$ (10,354)	\$ 2,535
Other comprehensive income (loss):				
Foreign currency translation adjustments	4,434	2,995	(29)	(786)
Comprehensive income (loss)	\$ 745	\$ 5,827	\$ (10,383)	\$ 1,749

CryoLife, Inc. and Subsidiaries
Financial Highlights
(In thousands)

	(Unaudited)		(Unaudited)	
	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Products:				
BioGlue	\$ 12,437	\$ 17,933	\$ 29,174	\$ 35,155
JOTEC	13,174	17,208	28,642	33,162
On-X	10,116	12,410	22,318	24,141
PhotoFix	880	935	1,922	1,665
PerClot	497	784	1,357	1,834
CardioGenesis cardiac laser therapy	164	1,898	275	3,612
Total products	37,268	51,168	83,688	99,569
Preservation services:				
Cardiac tissue	\$ 8,061	\$ 10,500	18,079	19,430
Vascular tissue	8,396	9,471	18,372	19,645
NeoPatch	46	--	61	--
Total preservation services	16,503	19,971	36,512	39,075
Total revenues	\$ 53,771	\$ 71,139	\$ 120,200	\$ 138,644
Revenues:				
U.S.	\$ 30,392	\$ 38,239	\$ 66,839	\$ 75,563
International	23,379	32,900	53,361	63,081
Total revenues	\$ 53,771	\$ 71,139	\$ 120,200	\$ 138,644

	(Unaudited)	
	June 30, 2020	December 31, 2019
Cash, cash equivalents, and restricted securities	\$ 126,118	\$ 34,294
Total current assets	287,121	187,390
Total assets	693,254	605,654
Total current liabilities	48,933	45,195
Total liabilities	396,698	319,958
Shareholders' equity	296,556	285,696

CryoLife, Inc. and Subsidiaries
Reconciliation of GAAP to Non-GAAP
Net (Loss) Income and Diluted (Loss) Income Per Common Share
(In thousands, except per share data)

	(Unaudited) Three Months Ended June 30,		(Unaudited) Six Months Ended June 30,	
	2020	2019	2020	2019
GAAP:				
(Loss) income before income taxes	\$ (4,766)	\$ 2,739	\$ (12,901)	\$ 1,089
Income tax benefit	(1,077)	(93)	(2,547)	(1,446)
Net (loss) income	\$ (3,689)	\$ 2,832	\$ (10,354)	\$ 2,535
Diluted (loss) income per common share	\$ (0.10)	\$ 0.07	\$ (0.27)	\$ 0.07
Reconciliation of (loss) income before income taxes, GAAP to adjusted net (loss) income, non-GAAP				
(Loss) income before income taxes, GAAP:	\$ (4,766)	\$ 2,739	\$ (12,901)	\$ 1,089
Adjustments:				
Amortization expense	3,000	2,557	6,033	5,136
Business development, integration, and severance expense	653	203	1,476	1,312
Corporate rebranding expense	--	--	321	--
Adjusted (loss) income before income taxes, non-GAAP	(1,113)	5,499	(5,071)	7,537
Income tax (benefit) expense calculated at a pro forma tax rate of 25%	(278)	1,375	(1,268)	1,884
Adjusted net (loss) income, non-GAAP	\$ (835)	\$ 4,124	\$ (3,803)	\$ 5,653
Reconciliation of diluted (loss) income per common share, GAAP to adjusted diluted (loss) income per common share, non-GAAP:				
Diluted (loss) income per common share, GAAP:	\$ (0.10)	\$ 0.07	\$ (0.27)	\$ 0.07
Adjustments:				
Amortization expense	0.08	0.06	0.16	0.13
Business development, integration, and severance expense	0.02	--	0.04	0.03
Corporate rebranding expense	--	--	0.01	--
Tax effect of non-GAAP adjustments	(0.02)	--	(0.05)	(0.03)
Effect of 25% pro forma tax rate	--	(0.02)	0.01	(0.05)
Adjusted diluted (loss) income per common share, non-GAAP	\$ (0.02)	\$ 0.11	\$ (0.10)	\$ 0.15
Diluted weighted-average common shares outstanding	37,520	37,838	37,455	37,789

CryoLife, Inc. and Subsidiaries
Reconciliation of GAAP to Non-GAAP
Revenues and Adjusted EBITDA
(In thousands, except per share data)

	(Unaudited)			(Unaudited)		
	Three Months Ended			Six Months Ended		
	June 30,			June 30,		
	2020	2019	Growth Rate	2020	2019	Growth Rate
Reconciliation of total revenues, GAAP to total revenues, non-GAAP:						
Total revenues, GAAP	\$ 53,771	\$ 71,139	-24%	\$ 120,200	\$ 138,644	-13%
Impact of changes in currency exchange	--	(1,095)		--	(1,723)	
Total constant currency revenues, non-GAAP	\$ 53,771	\$ 70,044	-23%	\$ 120,200	\$ 136,921	-12%

	(Unaudited)			(Unaudited)	
	Three Months Ended			Six Months Ended	
	June 30,			June 30,	
	2020	2019		2020	2019
Reconciliation of net (loss) income, GAAP to adjusted EBITDA, non-GAAP:					
Net (loss) income, GAAP	\$ (3,689)	\$ 2,832		\$ (10,354)	\$ 2,535
Adjustments:					
Depreciation and amortization expense	4,743	4,381		9,642	8,731
Interest expense	3,652	3,811		7,040	7,705
Stock-based compensation expense	2,510	2,266		5,074	4,119
Business development, integration, and severance expense	653	203		1,476	1,312
Corporate rebranding expense	--	--		321	--
Interest income	(66)	(233)		(168)	(349)
(Income) loss on foreign currency revaluation	(744)	176		2,919	250
Income tax benefit	(1,077)	(93)		(2,547)	(1,446)
Adjusted EBITDA, non-GAAP	\$ 5,982	\$ 13,343		\$ 13,403	\$ 22,857

CryoLife, Inc.
Second Quarter 2020 Earnings
Conference Call Transcript July 30, 2020

Greetings, and welcome to CryoLife's Second Quarter 2020 Financial Conference Call.

(Operator Instructions)

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Lynn Lewis from the Gilmartin Group. Thank you. You may begin.

Operator: Good afternoon, and thank you for joining the call today. Joining me today from CryoLife's management team are Pat Mackin, CEO; and Ashley Lee, CFO.

Before we begin, I'd like to make the following statements to comply with the safe harbor requirement of the Private Securities Litigation Reform Act of 1995. Comments made on this call that look forward in time involve risks and uncertainties and are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The forward-looking statements include statements made as to the company's or management's intentions, hopes, beliefs, expectations or predictions of the future. These forward-looking statements are subject to a number of risks, uncertainties, estimates and assumptions that may cause actual results to differ materially from those forward-looking statements.

Additional information concerning certain risks and uncertainties that may impact these forward-looking statements is contained from time to time in the company's SEC filings and in the press release that was issued earlier today.

With that, I'll turn the call over to CryoLife's CEO, Pat Mackin.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Hey, thanks, Lynn, and good afternoon, everyone. Thanks for joining.

The second quarter of 2020 was filled with a number of challenges as COVID-19 disrupted many facets of our lives. I'm very pleased to report our team responded to these unprecedented challenges with incredible dedication and resolve. I want to thank our entire organization for their outstanding performance, and we have a lot to be proud of.

As I will explain later in more detail, we were able to deliver a number of -- on our key objectives and initiatives and also deliver solid results. In Q2, we achieved total revenues of \$53.8 million, which reflects a decrease of 24% versus the second quarter of 2019 and a decrease of 23% on a constant currency basis. Our revenue decline this quarter was largely driven by the result of the delay -- in some cases, cancellation -- of procedures in April and early May in the various markets that we serve.

As hospitals in these regions began resuming procedures starting in May, our revenue likewise began to increase. In April, our revenue was down 39% compared to April of 2019. Our May revenue was down 22% compared to May of '19, and our June revenue was down 15% compared to June of 2019.

While it is impossible to forecast with certainty how COVID-19 will impact our business in the second half of the year, we are cautiously optimistic that we will see continued improvement in our revenue performance for Q3 and Q4 compared to the comparable prior year period. We also anticipate that we will begin to see the benefit from recently launched or soon-to-be-launched next-generation JOTEC products, as well as positive news on the regulatory approval front that should benefit us in 2021. Based on what we knew today, what we now know today, we expect 2021 to be a very strong year for CryoLife.

Once I've provided some color on our performance for Q2, as well as our expectations for the remainder of 2020, Ashley Lee, our CFO, will review our second quarter financial results and liquidity in greater detail. I will then make some closing comments and open up the line for questions.

First I will update you on the status of key aspects of our business, starting with operations. Since our last update, fortunately, little has changed as our operations have continued to run at or near capacity with few, if any, disruptions. We've been able to further our growth initiatives, fund key R&D projects, execute on a \$100-million convertible senior note offering which allowed us to repay our \$30-million revolving credit facility, and have more cash available for general corporate purposes.

Moving on to revenue performance for Q2. All in all, CryoLife has weathered the COVID-19 storm well due to, in large part, the fact that the vast majority of our products are used in procedures that cannot be postponed at all or that cannot be delayed for very long. As I indicated previously, revenue dipped sharply in April 2020 but then improved thereafter as Europe, Asia and certain U.S. geographies resumed more procedures, including those in which our products are used. As hospitals and providers have learned more in their ability to deliver healthcare even in the face of, and in some cases, a resurgence of the COVID-19 pandemic, we are optimistic that given the nature of our products we can deliver solid revenue performance for the back half of 2020 and enter '21 on very solid footing.

Our commercial team has shown that they can continue to supply devices and support procedures both in person and virtually, and employ creative solutions to ensure continued customer service and patient care. We expect their knowhow and expertise will further solidify our excellent reputation with customers and strengthen our leadership position in aortic repair. We will also continue to diligently manage our expenses while strategically investing for growth, now and when the pandemic subsides.

On the manufacturing front, we've continued to avoid any significant supply chain disruption, and each of our three manufacturing sites are functioning at or near capacity. At each of these sites, we have safety protocols that we've implemented earlier this year that remain in place. The slowdown in procedure also has allowed us to improve our JOTEC inventory position, and we remain on track to have our second source sewing supplier by the end of the year.

As Ashley will further detail in his remarks, we remain in a position of financial strength. In June, we completed a \$100-million convertible debt offering, using some of the proceeds to repay our \$30-million revolver.

In addition to our encouraging revenue performance in the quarter, good expense management and enhanced financial position, we made meaningful progress on several other initiatives. First, we made continued progress with our JOTEC product launches. As of the end of the second quarter, we initiated the limited market release for E-vita OPEN NEO and E-nside, and anticipate a limited market release for E-nya in October. We also resumed the limited market release for NEXUS. We expect -- we anticipate full market releases for all three new JOTEC products and later in 2020 and as we move into 2021. As we mentioned on our last call, our teams are continuing to gear up to train physicians. We're building supply to support the full market launches of the three JOTEC products, and we currently have sufficient NEXUS inventory for the remainder of the year.

Second, in May we announced the initial enrollments of the PROACT 10A trial, which is our prospective randomized clinical trial to determine if patients with the On-X aortic valve can be maintained safely and effectively on Eliquis versus warfarin. The trial is expected to enroll approximately 1,000 patients across 60 sites in North America. Enrollments occurred in the second quarter notwithstanding the pandemic, as some institutions continued to enroll patients in important clinical trials and patients did not need to have implant procedures to participate in the trial. As a result, if the trial meets its endpoints, we believe we can still achieve FDA approval for the use of Apixaban with the On-X aortic valve in 2024, and that the On-X aortic valve will become the market share leader in the mechanical valve market as well as take share from the existing bioprosthetic aortic valve market.

And lastly, on the regulatory front, we remain on track before year-end to file a PMA for PerClot in the U.S., and our response to the Chinese FDA for BioGlue.

With that, I will now turn the call over to Ashley for a detailed financial review of the quarter. Ashley?

David Ashley Lee - CryoLife, Inc. - Executive VP, COO & CFO: Thanks, Pat, and good afternoon, everyone. Total company revenues were \$53.8 million for the second quarter, down 24% compared to the second quarter of 2019, due primarily to the impact on our business from COVID-19 and the absence of TMR revenues. As Pat mentioned, we saw monthly sequential improvement for procedure volumes and revenues this past quarter. In the second quarter of 2020 versus the second quarter of 2019, tissue processing revenues decreased 17%, On-X revenues decreased 18%, BioGlue revenues decreased 31% and JOTEC revenues decreased 23%. Performance in each of these product lines was adversely affected by, primarily, the COVID-19 pandemic.

Our gross margins were 67% for the second quarter, compared to 66% for the second quarter of 2019. The improvement in gross margins primarily reflects a reduction in unit cost of products and tissues shipped during the second quarter of 2020 as compared to the second quarter of 2019.

On the bottom line, we reported a net loss of approximately \$3.7 million, or \$0.10 per fully diluted share, in the second quarter of 2020. Non-GAAP net loss was \$835,000, or \$0.02 per share. Please refer to our press release for additional information about our non-GAAP results, including a reconciliation of these results to our GAAP results.

As of July 24, 2020, we had approximately \$127 million in cash and cash equivalents. Cash reflects the \$100-million convertible debt financing we completed during the quarter, less expenses, for a net of \$96.5 million received, as well as the repayment of the full \$30 million drawn under our revolving credit facility.

Even though we are very encouraged by what we are seeing regarding the recovery of our business, uncertainty remains regarding the impact that COVID-19 may have on our business over the balance of this year and thereafter. To be prudent, we will continue to monitor our expenses very carefully during Q3 and Q4.

We shared our cost reduction initiatives with you on our previous call; those include hiring freezes, reductions in discretionary spending, restrictions on nonessential business travel, deferment of merit increases for top members of management, reductions to cash compensation for our board members for a six-month period, and a temporary slowdown of most clinical and R&D programs that are not directly connected to anticipated revenue generation before 2023. However, we are continuing to invest in clinical and R&D programs related to products that we expect to deliver revenue in '21 and '22, including our U.S. PerClot PMA, BioGlue China and PROACT mitral regulatory approvals.

With the recovery we are experiencing in the business and the cost initiatives that we have implemented, we remain confident that we not only have adequate liquidity to run the business, but also have sufficient capital to support our growth initiatives and comfortably service our debt. Due to the potential for continued uncertainties from the impact of COVID-19, we will not be issuing 2020 financial guidance at this time.

I will turn the call back over to Pat for his closing comments.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Thanks, Ashley. So in summary, as you've heard today, our growth has been somewhat delayed but far from derailed. There is little question at this point how important our products are to customers and patients alike. We continue to estimate that our business is mostly comprised of products and procedures that cannot be postponed, or if they are postponed, only for a limited amount of time. Our next-generation JOTEC offerings are very exciting products, and we're very optimistic about their prospects.

With that, I'd now like to turn it over back to the operator to open the line for questions.

Operator: Our first question comes from the line of Cecilia Furlong with Canaccord Genuity.

Cecilia E. Furlong - Canaccord Genuity Corp., Research Division – Associate: I guess I'd like to start with PROACT and the trial, and really just what you've seen in terms of interest levels to potentially pull patients into just being implanted ahead of a potential indication. I guess just any interest that you've seen broadly from the trial starting.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, so I think one of the great things about this trial is that you don't, and as I mentioned in my comments, you actually don't need to go have a heart valve put in. This trial is very unique in that these are patients who already have On-X aortic valves, so there's about 10,000 of them in the U.S. kind of in the time period that we're enrolling in the trial, or are available to enroll in the trial.

So the very first patient that was enrolled during the pandemic actually was enrolled during a telehealth appointment. See, they didn't have to go to the hospital, they didn't have to go to the doctor. They did all their informed consent and all the paperwork over a telehealth appointment on video and then had their drug shipped directly to their house. So this trial, if there was any trial that was designed to be implemented in a pandemic, is one of them.

So I think there's a couple points to think about with this trial. One, we have tremendous patient interest in this trial, for obvious reasons. If you've ever talked to anybody who's on Eliquis or who has been on warfarin, it's like night and day, and patients are very excited about the opportunity to be -- this study presents -- to be able to potentially use Eliquis in the future. So one, there's a lot of excitement.

Two, there was a natural slowdown in some centers that were hit very hard by the pandemic in April and May. So for example, big centers in New York City that were kind of being overwhelmed with COVID patients, they were not bringing in any new clinical trials. So it had nothing to do with the interest or excitement about the trial; it was more just they obviously had other priorities going on.

I think the second thing is, we made a conscious decision, as Ashley made in his remarks, that we obviously tightened our belt on expenses in the second quarter because no one really knew what the revenue picture was going to look like. The PROACT 10A is our largest spend in the company; it's about \$6 million, so we kind of ratcheted back the spending from about \$6 million to \$3 million, so we cut it in half. So we actually had a natural governor that we put on the trial.

We're exploring now, as things start to loosen up with clinical centers, as well as our confidence around the revenue performance, we're going to look to accelerate the enrollment in the trial. So again, there was a lot of things going on, but I think we're as excited as ever about the overall interest and opportunity for that trial.

Cecilia E. Furlong - Canaccord Genuity Corp., Research Division – Associate: Great, thank you. And I guess if I could just ask, as well, about NEXUS, just if you could provide some commentary on what you're really seeing in Europe in the early days.

And then, just as you think about the U.S. opportunity, your updated thoughts around the trial, trial timing, and then just priority within the rest of your pipeline, longer-term pipeline, as you reevaluate everything just in this COVID period. Thank you.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes. So just as a refresher, NEXUS is a very sophisticated endovascular device that's produced by a company called Endospan, who is an Israeli startup company that we entered into a transaction with several months ago, and that's all in press releases and presentations. It's the first device ever that allows a patient to be treated with a catheter to fix the aortic arch in a branch vessel, so it's a very sophisticated technology.

Because it's so sophisticated, when we rolled out the product, it required, for good reason, that you have a physician proctor or trainer fly from -- fly in to support the new physician who is in training. And of all of our products, this is probably the one that got hit the hardest during the pandemic, so I'll just give you an example. We were building a great case pipeline of patients and surgeons who were getting trained, and we were bringing patients on back in January and February, and when the pandemic started kind of hitting hard, particularly in Italy and Spain, as you recall, back in March, nobody was flying. No surgeons. In some places, the elective cases were canceled. But the idea of a proctor flying from Milan to Madrid just wasn't going to happen. So NEXUS has clearly taken a setback because of the pandemic and because of the requirement of our physician proctors to travel, and the lack of travel where physicians just aren't traveling. So that's a short-term thing. We're starting to see cases pick back up in certain parts of Europe. But we're extremely bullish on that technology.

And as far as the U.S. IDE trial, just to remind you of the relationship we have with Endospan; so we paid \$10 million for the European rights for five years. We also funded them with milestones to fund the U.S. trial up to \$15 million. And they're in current -- so the company Endospan is responsible for the U.S. IDE trial, and they've been in discussions with the FDA about their IDE protocol. I'm not exactly sure what the timing is, but again, obviously COVID has somewhat slowed down the FDA in some regard. But we feel like that trial should start, probably, at the beginning of 2021. And it's one of the first of its type device ever, so we think there will be a lot of excitement for the enrollment in that trial as well.

Operator: Our next question comes from the line of Suraj Kalia with Oppenheimer.

Suraj Kalia - Northland Capital Markets, Research Division - MD and Senior Research Analyst: So Pat, just hopping in between calls -- forgive me if I missed some numbers. Did you provide an update on On-X mitral?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: I did not. So On-X mitral, just to give you a quick update, On-X mitral completed its enrollment as a 400-patient trial that completed its enrollment at the end of last year. And basically, we are using all of 2020 as the one-year follow-up period. So we should complete -- the last patient should hit one year probably, I think, in the December time frame. And then we will basically take a quarter to crunch the data and then we'll be submitting the PMA, probably in Q2, for that approval.

Suraj Kalia - Northland Capital Markets, Research Division - MD and Senior Research Analyst: Got it. And Pat, this might be in the weeds, but did you provide the number of patients enrolled so far in PROACT 10A? And also, curiously --

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: We did not. Yes, we haven't given that update. And I think part of it, too, is -- I don't know if you heard my comments on the previous -- in the previous question, but there was a couple things that were kind of slowing down the trial. One, as you well know, a lot of these big centers, for example in New York City, and many of the big centers in New York are in this trial -- I mean, they literally were not even opening new trials because of what was going on in the second quarter.

Second -- in fact, I said that the first patient that was enrolled was done via telehealth, so this is a perfect trial for a pandemic. But we're also trying to be financially prudent, right? So we weren't sure what Q2 was going to look like, so we really tightened up our belt on the expenses. So we kind of pulled back probably about half the funding for the trial, so we actually had a natural slowdown on the number of centers we were turning on, and it's not due to a lack of interest; it was more just making sure that we conserved cash. And based on our performance and our discipline around spending, we actually performed extremely well in the quarter and believe our financials will look even better as we go into the second half. So I think we will look to open up the funding for that trial going forward.

Suraj Kalia - Northland Capital Markets, Research Division - MD and Senior Research Analyst: Got it. And Pat, in terms of U.S.-OUS dynamics, would love to get your perspective, specifically OUS. I'm curious what the status is for the JOTEC supply disruption. And in the U.S. specifically, any color you can provide -- and forgive if you've mentioned this -- about resurgence in Florida, Texas and Arizona? Our field checks are telling us things are pretty dicey in a lot of the hospitals. I'd love to have you provide some color on what you all are seeing in the U.S. as a whole and maybe in some pockets also? Thank you very much for taking my questions, and congrats on a nice quarter.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, and it's -- yes, thanks, Suraj. It's -- I think one thing I can say, and I'm probably sure most companies would say the same thing -- I mean, if you've seen one geography, you've seen one geography, right? So for example, Asia was probably our best-performing versus last year in the second quarter because the -- China went through a -- and we also don't have a huge business in Asia, but we actually saw Asia return to normal kind of first. Our worst performer was Latin America, because Brazil got hit hard and hit late, and we have a big -- a fairly good-sized operation in Brazil. The U.S. actually recovered, I would say, very strong. We've seen -- and really, across the board, we've seen very strong kind of return to getting back to normal in the U.S.

In fact, I actually looked at the month of July, right, with this resurgence going on. I looked at the month of July. I looked at Florida, I looked at Texas, I looked at Arizona. We're actually doing better than last year in Florida, so go figure. I mean, I can't explain it. Texas is actually doing worse than last year. So again, it's -- part of it depends -- so for example, you think about Houston as a huge cardiac hub. So the fact that Houston got hit hard and that's a big cardiac hub, that does -- it makes a lot of sense that your numbers would be off of last year. Parts of Florida could be stronger where they're not having as big outbreaks.

So we are not -- I mean, I think one of the things I can say for CryoLife products, this resurgence, we are not seeing a return to the April, early May type stuff. And I think one of the things that hospitals have figured out is kind of how to manage -- I think this idea of shutting everything down and not -- letting all your elective procedures go away, I just don't think that's something they're going to return to, particularly on the cardiac side, where, as I commented, half of our portfolio you can't delay and the other half you can't delay very long. So we're actually not seeing a big negative impact from the resurgence.

I would say, on the European side, again, the U.K. obviously got hit later and hard; they've been slower to return. Germany did a very good job managing the pandemic and they're kind of returning very quickly. So it's really kind of region-dependent. But overall, I mean, we've seen -- if you went on -- I mean, we saw April -- the April numbers were down 39%, May was down 22%, June was down 15%, and we're seeing better numbers now. So we certainly seem to be doing quite well as the time goes by.

Suraj Kalia - Northland Capital Markets, Research Division - MD and Senior Research Analyst: And Pat, the JOTEC supply issue resolved?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, I would say -- I mean, one of the -- unfortunately, this pandemic obviously has been terrible for lots of people around the world. One of the silver linings has been with the numbers I just read to you. So having the quarter off by 24%, and we kept the factories running hot, our JOTEC inventory is up 32% now. So we have taken the opportunity with this pandemic to keep our supply chain, and our head of operations has done a fantastic job. And we didn't have a COVID-positive case in one of our factories for almost 100 days. In talking with other people in the industry, that was kind of unheard of. And we've been very disciplined about our safety protocols for our employees. So our JOTEC supply is -- we aren't seeing the supply issues, #1. #2, we're continuing to build and run the factories hot, and #3, our second source supplier should be online by the fourth quarter, so we think the JOTEC supply will be a thing of the past.

Operator: Our next question comes from the line of Mike Matson with Needham & Company.

Operator -- This is David Saxon on for Mike. I appreciate the detail you gave on the monthly revenue growth trends during the quarter. Would you mind sharing what you saw in July? And then also, what you're seeing in regions like the Northeast that were hit earlier on and what you're seeing on the pace of recovery in those regions?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes. I mean, we're not going to give specific July numbers. Again, I commented on Q2 that -- I'll make a general comment, and you can kind of go from there. We know how you guys love to kind of pin us down with this stuff. But we went from negative 39% April, negative 22% May, negative 15% June, and we're doing better than that in July. So that's as far as I'm going to go with that.

Operator -- Okay, that's great. And then just in terms of the pace of recovery in regions like the Northeast?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes. Ashley, do you want to -- I looked at a bunch of the different numbers. We ran -- I don't know, Ashley, if you have anything at your fingertips with the Northeast in July versus last year?

David Ashley Lee - CryoLife, Inc. - Executive VP, COO & CFO: No, I don't have that right at my fingertips, but the Northeast is doing extremely well. I don't recall, off the top of my head, whether it is, I would say, back to level par with last year, but the recovery has been really strong in the Northeast.

Operator - - Okay, appreciate the color. And then on the Misonix distribution agreement, I know it's early days, but what's the feedback then on the NeoPatch, and how should we think about that contribution during the balance of the year?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, we've actually -- there's been great -- I mean, we've had really good customer feedback. I mean, Misonix has got an excellent sales force in the channel in which these products are served, in a wound care segment, so we're very excited about the relationship with them. Obviously, like everybody else, we all got hit in the second quarter, which slowed down -- it was right when we were doing our launch. So I think that they're -- in our recent discussions with them, they're ramping up for kind of a relaunch as things kind of get back to normal. And we'll give more color on that for 2021 when they've had a chance to kind of roll out their launch and things can -- as we see things progress. But we haven't given specific numbers out on that, but we do expect to do that for 2021.

Operator: Our next question comes from the line of Jeffrey Cohen with Ladenburg Thalmann.

Jeffrey Scott Cohen - Ladenburg Thalmann & Co. Inc., Research Division - MD of Equity Research: So one follow-up to -- as far as NeoPatch goes. Any kind of further data that we can garner from the company as far as what areas, of therapeutic areas, that they've been implanting in? Wound, hand, ankle, ortho, neuro?

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, so their major focus is on the wound care, which is where the publication was used. Also, they have a good surgical sales force, a hospital-based surgical team, so I do -- I believe there's going to be some foot and ankle usage in that regard as well. So again, we can give more of an update -- we were waiting to let them go through their kind of limited market release and then talk about what we're going to -- what they're looking for in 2021.

Jeffrey Scott Cohen - Ladenburg Thalmann & Co. Inc., Research Division - MD of Equity Research: Okay, got it. On the G&A, as you said earlier that you're running hot, so that's going to continue through Q3? And I guess a question related to that on the inventory -- Ashley, any ramifications or any commentary from Q2 inventory as far as the manufacturer side? And any read into Q3?

David Ashley Lee - CryoLife, Inc. - Executive VP, COO & CFO: No, first of all, on the G&A, and just OpEx in general, I think as Pat mentioned earlier in the call, we are very optimistic about the second half of the year to see continued recovery in the business. And we're not giving out any financial guidance, but I think clearly, we're managing our expenses throughout 2020 to -- in response to how we're seeing the business recover.

Pat mentioned one thing in regards to spending on projects. We're looking at starting to accelerate spending on, among other things, the PROACT 10A trial. On the G&A side, we've delayed a lot of G&A spending throughout the year. It will -- certainly in the second quarter. And again, the level of spending in the third and fourth quarters are really going to be tied to what we see in the recovery on the top line. So no specific guidance, but more general, but it's going to be tied to the recovery.

In regards to inventory, Pat mentioned that we've been running hot in all areas of manufacturing all throughout the second quarter, and it's starting to manifest itself in improved inventory levels with JOTEC. We're seeing some increases in some of our other product lines as well. But it's something that we're going to manage as we go throughout the balance of the year. We're going to continue to run our factories at or near capacity, and if the business hopefully recovers throughout the year, we'll likely continue to do that. If it does not, then we will likely curtail some of our manufacturing if need be. But again, everything's going to be tied to how well the business recovers during the third and fourth quarter.

Operator: There are no further questions in the queue. I'd like to hand the call back to Mr. Mackin for closing remarks.

James Patrick Mackin - CryoLife, Inc. - Chairman, President & CEO: Yes, so again, thanks for joining the call today. And as you could hear from the numbers, things progressed, continually got better from April to May to June, and we're seeing even better in July. Our clinical projects are on track, our R&D projects are on track, we've got our limited market releases for the three JOTEC products, we've got NEXUS coming back online, we've got the

NeoPatch which was brought up, we've got PROACT 10A, we've got the PROACT mitral. And frankly, when you look at our financial performance and the discipline we've had around spending, we are not really anticipating needing to burn much cash at all in the second half.

So we're in a very strong liquidity position, and we'll just continue to -- none of us can predict what's going to happen with the virus, but we know that our portfolio is resilient and we'll be financially disciplined when we need to be, and we will accelerate opportunities when we see that the business is returning. So we appreciate your interest in the company and look forward to catching up with you on the next call. Thanks.

Operator: Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation. You may disconnect your lines at this time, and have a wonderful day.
