

**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): **June 5, 2023**

CVRx, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-40545
(Commission
File Number)

41-1983744
(I.R.S. Employer
Identification No.)

9201 West Broadway Avenue, Suite 650
Minneapolis, MN 55445
(Address of principal executive offices) (Zip Code)

(763) 416-2840
(Registrant's telephone number, including area code)

N/A
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value \$0.01 per share	CVRX	The Nasdaq Global Select Market

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 x

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.

Item 5.07 Submission of Matters to a Vote of Security Holders.

On June 5, 2023, CVRx, Inc. (the “Company”) held its 2023 annual meeting of stockholders (the “Annual Meeting”). Voting results for each matter submitted to a vote at the Annual Meeting are provided below.

Proposal 1. Election of Directors. The two nominees for Class II director were elected to serve until the 2026 annual meeting of stockholders and until their successors are duly elected and qualified, by the votes set forth in the table below.

Nominee	For	Withheld	Broker Non-Votes
Kevin Hykes	12,368,856	617,120	5,809,856
Joseph Slattery	11,896,881	1,089,095	5,809,856

Proposal 2. The stockholders ratified the appointment of Grant Thornton LLP as the Company’s independent registered public accounting firm for the fiscal year ending December 31, 2023, by the votes set forth in the table below.

For	Against	Abstain
18,785,665	641	9,526

Item 7.01. Regulation FD Disclosure.

The Company intends to present the presentation materials attached hereto as Exhibit 99.1, and incorporated herein by reference, at the 43rd Annual William Blair Growth Stock Conference on June 8, 2023 and related investor meetings.

The information contained in this Item 7.01, including Exhibit 99.1, is being furnished and shall not be deemed to be “filed” with the Securities and Exchange Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Presentation of CVRx, Inc., dated June 8, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

CVRx, Inc.

Date: June 8, 2023

By: /s/ Jared Oasheim
Name: Jared Oasheim
Its: Chief Financial Officer

CVRx[®]

43rd Annual William Blair Growth Stock Conference,
June 2023



CVRx[®]
Outsmart the heart

Cautionary Note Regarding Forward-Looking Statement

This presentation by CVRx, Inc. (the "Company") contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including statements regarding our future financial performance (including, specifically, our 2023 expected operating and financial results), our anticipated growth strategies, anticipated trends in our industry, our business prospects and our opportunities. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

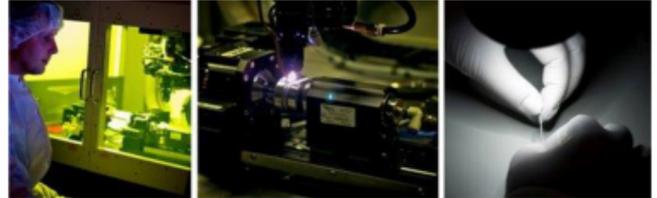
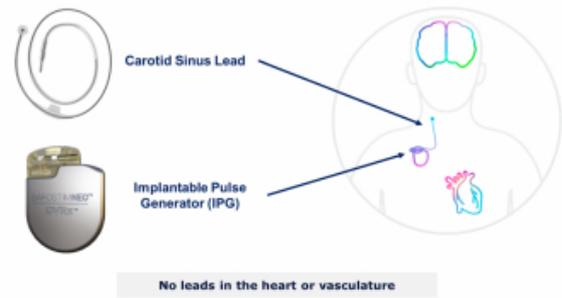
The forward-looking statements in this presentation are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this presentation and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our history of significant losses, which we expect to continue; our limited history operating as a commercial company and our dependence on a single product, Barostim; our ability to establish and maintain sales and marketing capabilities; our ability to demonstrate to physicians and patients the merits of our Barostim; any failure by third-party payors to provide adequate coverage and reimbursement for the use of Barostim; our competitors' success in developing and marketing products that are safer, more effective, less costly, easier to use or otherwise more attractive than Barostim; any failure to receive access to hospitals; our dependence upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers; a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide, including the outbreak of the novel strain of coronavirus, COVID-19; any failure of clinical studies for future indications to produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere; product liability claims; future lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and ultimately unsuccessful; any failure to retain our key executives or recruit and hire new employees; and other important factors that could cause actual results, performance or achievements to differ materially from those that are found in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Market & Industry Data

This presentation includes market and industry data and forecasts that the Company has developed from independent research reports, publicly available information, various industry publications, other published industry sources or the Company's internal data and estimates. Independent research reports, industry publications and other published industry sources generally indicate that the information contained therein was obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Although the Company believes that the publications and reports are reliable, the Company has not independently verified the data and makes no representation or warranty with respect to the accuracy of such information.

Company Overview

- **CVRx has the first and only FDA-approved device leveraging the power of the brain to treat cardiovascular diseases**
- **Barostim was approved by FDA in 2019 for a \$1.4 billion annual U.S. market opportunity in heart failure**
- **Proven management team leading 180+ employees**
- **Manufacturing capacity is 5,000 systems per shift per year at facility in Minneapolis, MN**
- **Strong financial profile with 80%+ gross margin**
- **Well-capitalized balance sheet with over \$100 million in cash (as of March 31, 2023)**



CVRx Management Team



Nadim Yared
President & Chief Executive Officer



Jared Oasheim
Chief Financial Officer



Paul Verrastro
Chief Marketing & Strategy Officer



Craig Palmer
Senior Vice-President of US Sales



Liz Galle
Vice-President of Clinical Research



Thomas Hengsteler
VP, European Sales & Marketing



Paul Pignato
VP, Operations



Jonelle Burnham
VP, General Counsel



Al Crouse
VP, Quality Assurance and Regulatory Affairs

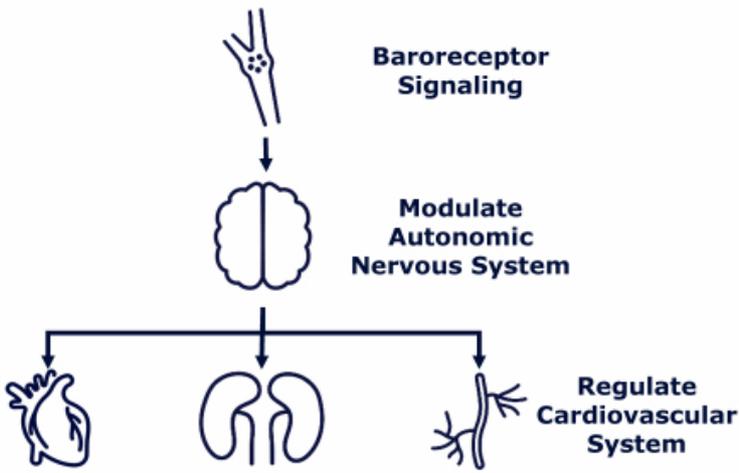


Ivana Stojanovic
VP, Market Access and DTC Marketing

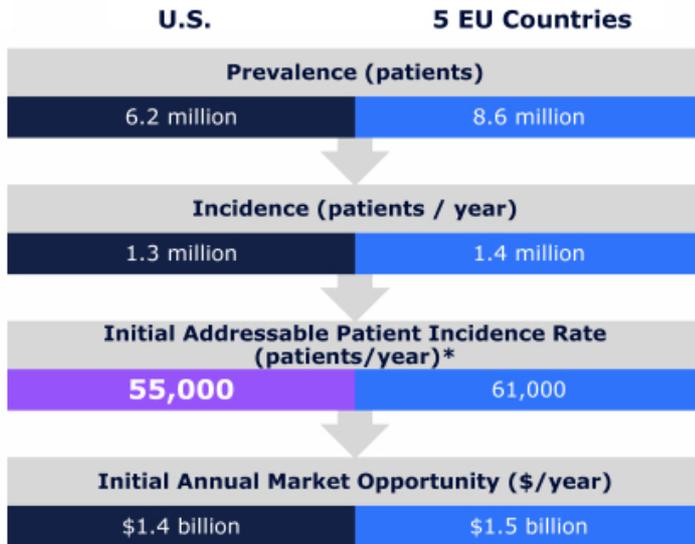


Jim Georgakopoulos
Distinguished Scientist

Baroreflex is integral to maintaining cardiovascular homeostasis



1. Large Market Opportunity



* NYHA III & II (with a recent history of III); LVEF ≤ 35%; NT-proBNP < 1600pg/ml; mentally and clinically fit; not indicated for CRT

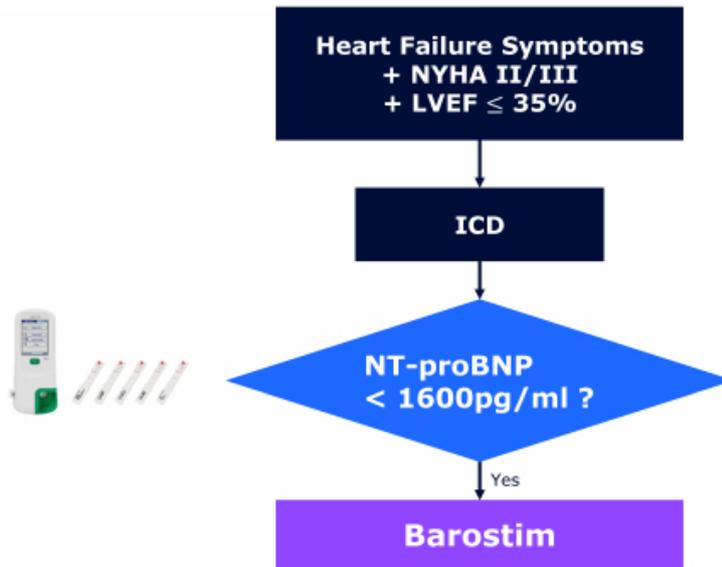
Initial Annual Market Opportunity from U.S. and largest 5 countries in Europe with initial addressable HFREF patient population



Assumptions:

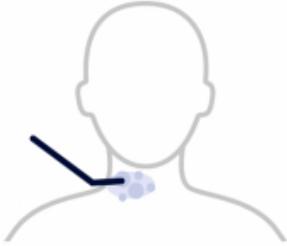
- (1) Average selling price of \$25,000
- (2) Excludes replacement market of approx. 30-40% of de novo market in the future (+\$0.9B-\$1.2B)
- (3) Market data reflects our estimates involving a number of assumptions and limitations

2. Straightforward Patient Identification



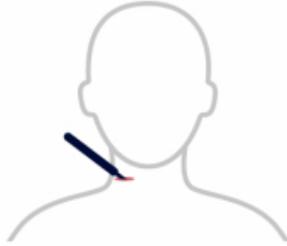
3. One-hour Outpatient Procedure

1 Preparation

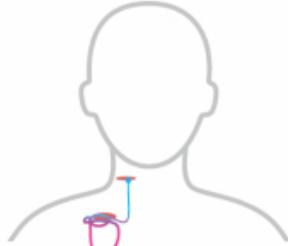


Starts like a standard endarterectomy, without opening any artery

2 Lead Placement

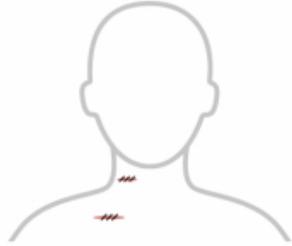


3 IPG Placement



Ends like a pacemaker or ICD procedure, without any hardware in the heart

4 Closure



4. Favorable Hospital Economics

Payment

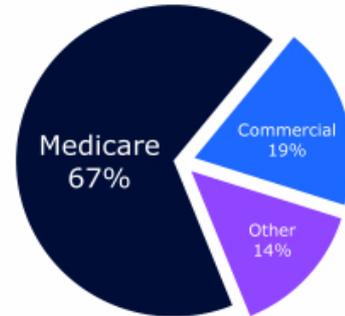
- CMS granted Barostim add-on payments for outpatient procedures (Transitional Pass-Through or TPT)
- TPT is hospital-specific:

CPT Code	CPT Code Description	2023 Medicare National Average Payment*
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	\$29,358** + TPT
0272T 0273T	Interrogation device evaluation (in person), with interpretation and report	\$145

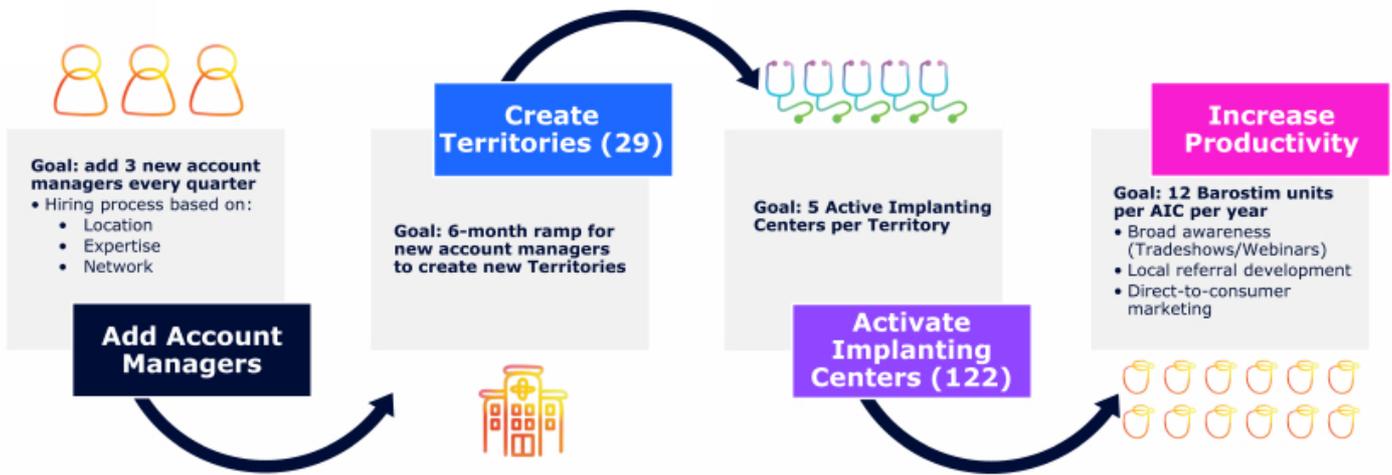
* Payment codes such as APC 5465 are indexed to adjust for cost of living and thus vary by location. These payments generally cover the hospital's costs for the device and the implantation procedure.
** APC 5465 was \$29,445 for CY2021 and \$30,063 for CY2022.

Coverage

- Claim-by-claim adjudication allowed by CMS in all 7 MACs since July 2020
- Transitional Pass-Through (TPT) carries a presumption of coverage

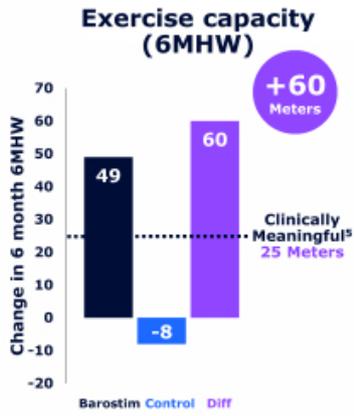


5. Proven Go-to-market Strategy

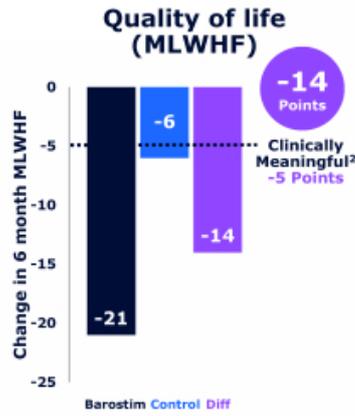


GOAL: Account Manager target
5 x 12 = 60 units per year x \$25K = \$1.5 million annual revenue

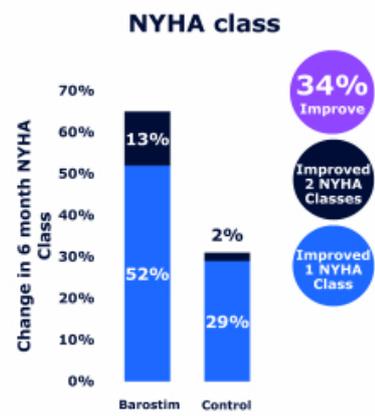
BeAT-HF Pre-Market Trial: 6-Month Symptom Improvement¹



CRT trial results		
CONTAK CD ³	NYHA III or IV LVEF ≤ 35% QRS > 120ms	39
MIRACLE ⁴	NYHA III or IV LVEF ≤ 35% QRS > 130ms	29



CRT trial results		
CONTAK CD ³	NYHA III or IV LVEF ≤ 35% QRS > 120ms	-11
MIRACLE ⁴	NYHA III or IV LVEF ≤ 35% QRS > 130ms	-9

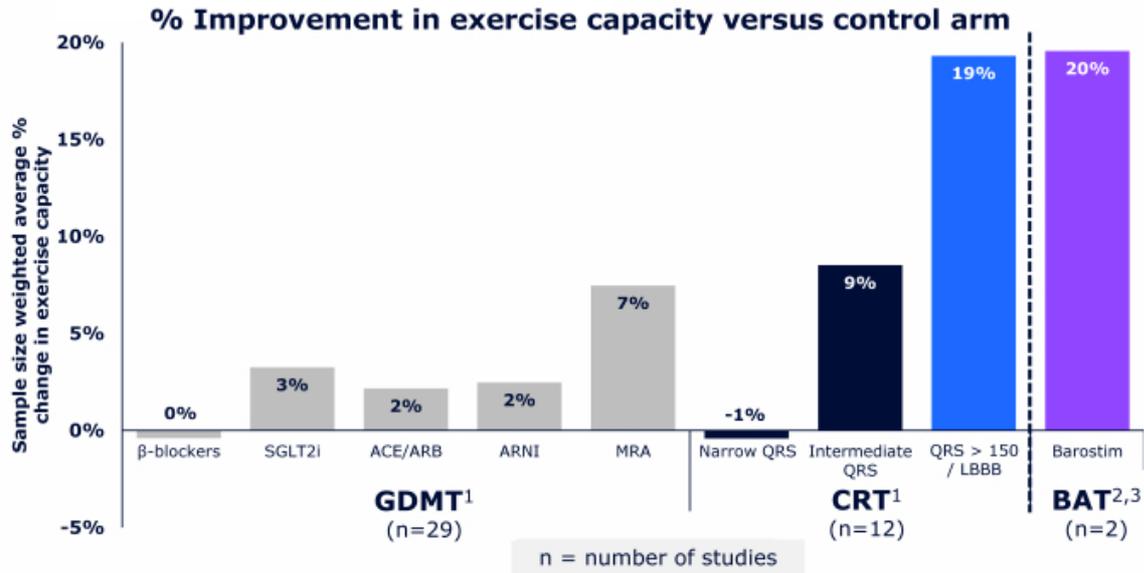


CRT trial results		
CONTAK CD ³	NYHA III or IV LVEF ≤ 35% QRS > 120ms	20%
MIRACLE ⁴	NYHA III LVEF ≤ 35% QRS > 130ms	30%

*Data from different studies and different patient populations may not be directly comparable

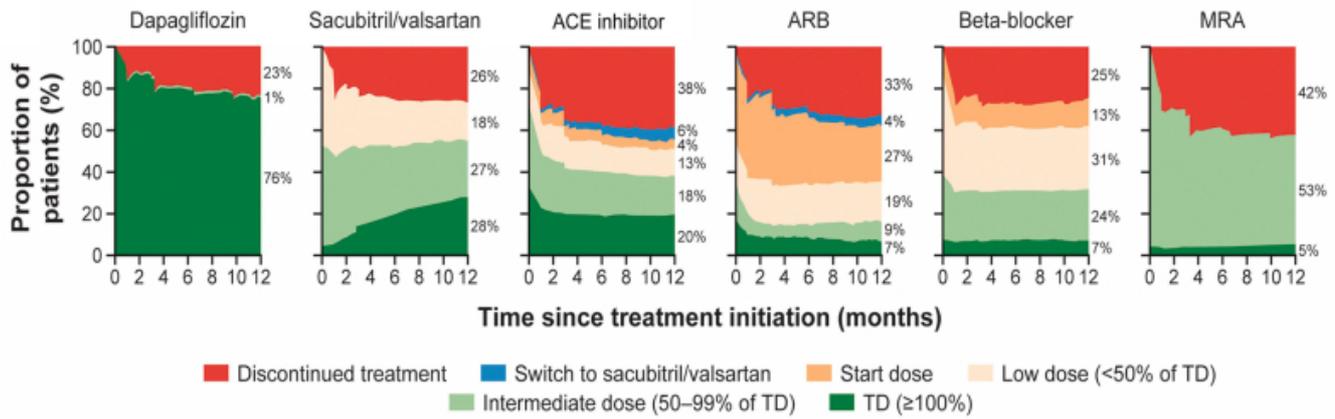
1. Zile MR, et al. J Am Coll Cardiol. 2020; 76:1-13.
2. Rector TS, et al. J Card Fail. 1995;1(3):201-216.
3. Higgins SL, et al. J Am Coll Cardiol. 2003;42:1454-1459.
4. Abraham WT, et al. N Engl J Med. 2002;346:1845-1853.
5. Gremeaux V, et al. Arch Phys Med Rehabil. 2011;92(4):611-619.

GDMT produces modest improvements in exercise capacity compared to CRT (QRS>150ms) and BAT



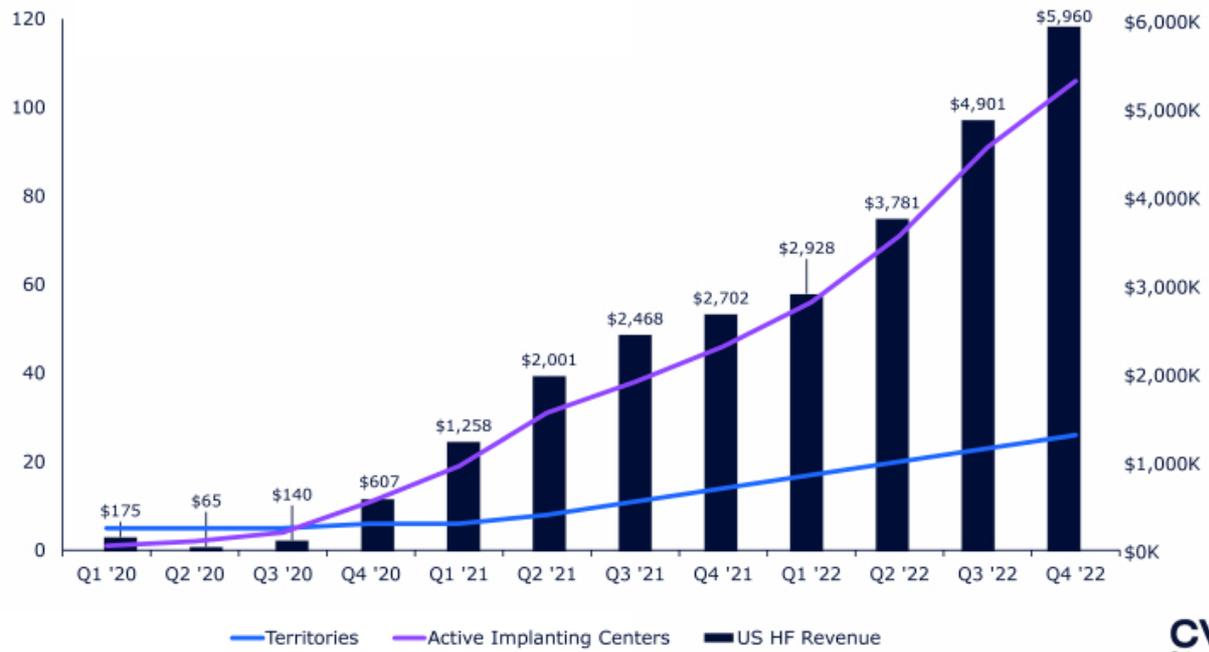
12 1. Adapted from Lewis G et al, Developments in Exercise Capacity Assessment in Heart Failure Clinical Trials and the Rationale for the Design of METEORIC-HF. Circ Heart Fail. 2022 May; 15(5):510-524; 2. Abraham WT, Zile MR et al. JACC: Heart Failure 2015 June; 3(6):487-496; 3. Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13

Tolerance, titration and discontinuation of GDMT

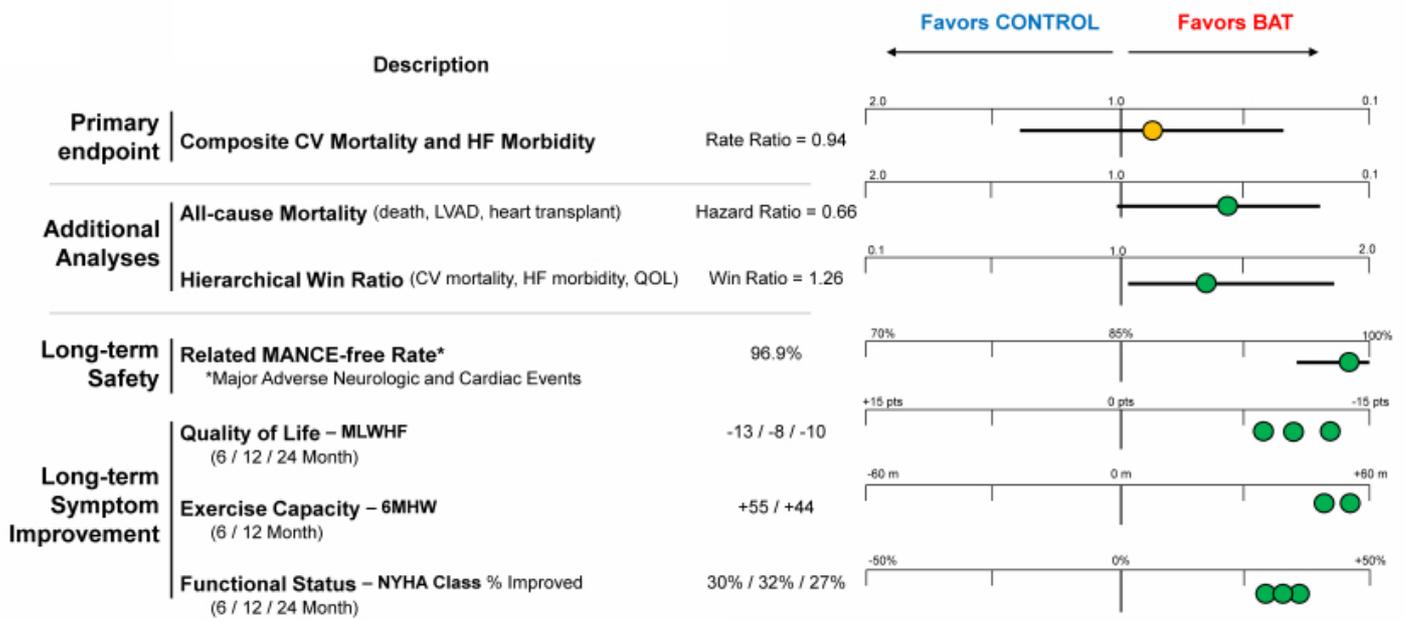


Large proportions of the HF patient population remain under target dose or have discontinued GDMT at 1 year

US Heart Failure Sales Achieved with 6-Month Data



BeAT-HF Summary of Key Evidence



Conclusion

Totality of evidence indicates that BAT is a safe, effective and durable treatment for patients with heart failure with reduced ejection fraction

Key takeaways

- Barostim is currently FDA-approved for the improvement of heart failure symptoms based on the pre-market phase of BeAT-HF at 6 months.
- The post-market phase of BeAT-HF confirmed the long-term durability of safety and symptomatic improvements, and the sustainability of the extent of the improvements.
- The reduction of all-cause death, LVAD and heart transplant is meaningful (34% reduction, nominal p-value 0.054).
- The pre-specified hierarchical composite endpoint was well balanced, and demonstrated meaningful benefit (Win ratio = 1.26, nominal p-value=0.04), stable over multiple sensitivity analyses.



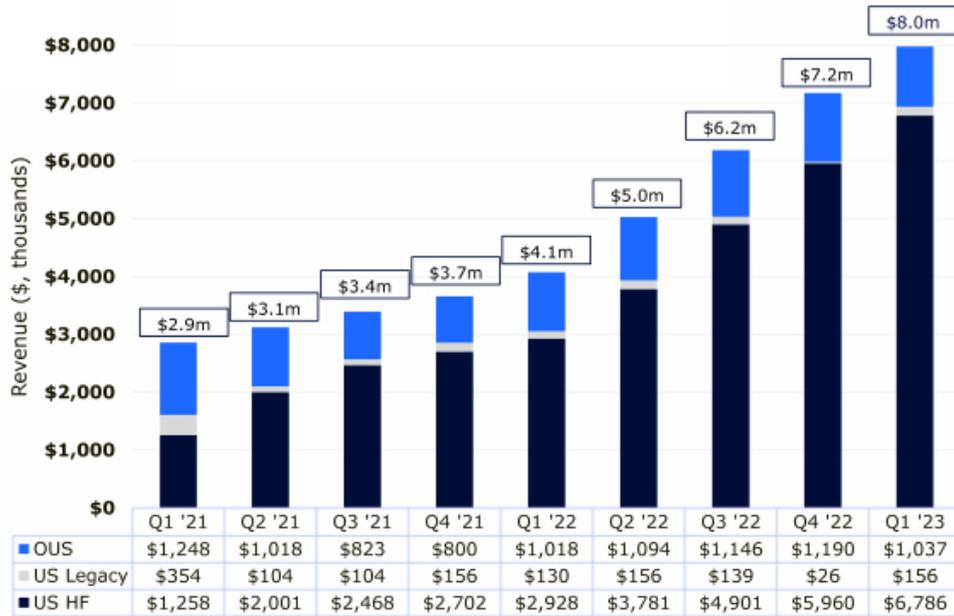
Next steps

- One or more manuscripts will be written by the executive steering committee for submission to peer-reviewed journals.
- The PMA-Supplement Clinical report has been submitted to FDA on 6/5/23, to seek an expansion of the labeling, commensurate with the recommendation of the Executive Steering Committee of BeAT-HF. We agree with the committee that the totality of evidence, despite a potential impact of COVID, supports the use of Barostim as a treatment for heart failure.
- A collaborative effort between CVRx, FDA and key academic institutions will continue analyzing the impact of COVID on heart-failure clinical trials, particularly on BeAT-HF.

US Heart Failure Sales Growth Continues



Financial Results



Highlights

Q1 2023

- Revenue: \$8.0M
- US HF Revenue: \$6.8M (+132%)
- US HF ASP: \$30.2K
- Gross Margin: 83%
- 3/31 Cash: \$103M

Apr/May – Momentum Continues

Full Year 2022

- Revenue: \$22.5M
- US HF Revenue: \$17.6M (+108%)
- US HF ASP: \$29.9K
- Gross Margin: 78%

2023 Guidance as of April 27, 2023

- **For the full year of 2023, we expect:**
 - Total revenue between \$35.5 million and \$38.0 million;
 - Gross margin between 80% and 83%;
 - Operating expenses between \$76.0 million and \$80.0 million

- **For the second quarter of 2023, we expect total revenue between \$8.2 million and \$8.8 million**

Questions?



CVRx
Outsmart the heart