UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

OKLAHOMA POLICE PENSION AND RETIREMENT SYSTEM, on behalf of itself and all others similarly situated, Plaintiff, v. CVRX, INC., KEVIN HYKES, NADIM YARED, JARED OASHEIM, AND ROBERT JOHN, Defendants.	**Civ. No. 26-cv-4746** **CLASS ACTION** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff Oklahoma Police Pension and Retirement System, on behalf of itself and all others similarly situated, by and through its counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, counsel's investigation, which includes, among other things: (a) review and analysis of regulatory filings made by CVRx, Inc. ("CVRx" or the "Company") with the U.S. Securities and Exchange Commission (the "SEC"); (b) press releases, presentations, and media reports issued by and disseminated by the Company; (c) analyst and media reports concerning CVRx; and (d) other public information concerning CVRx.

I. INTRODUCTION

1. This is a securities class action on behalf of persons and entities that purchased shares of CVRx's common stock between July 25, 2023, and August 6, 2026,

inclusive (the "Class Period"). The claims asserted herein are alleged against CVRx and certain of the Company's current and former officers under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5, promulgated thereunder.

2. CVRx is a commercial-stage medical device company focused on developing, manufacturing, and commercializing minimally invasive neuromodulation solutions for patients with cardiovascular disease. CVRx manufactures, markets, and sells an implantable medical device called Barostim. Barostim is the first medical technology approved by the U.S. Food and Drug Administration (the "FDA") that uses neuromodulation to "improve the symptoms" of patients with heart failure.

3. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's financial results and business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (a) to induce sales growth, CVRx and/or its employees were engaged in illegal and unsustainable sales practices, including improperly marketing Barostim, offering or paying kickbacks, and providing false information to government health insurance programs in violation of the False Claims Act ("FCA") and Anti-Kickback Statute ("AKS"); (b) CVRx's revenues were in part the product of such unlawful conduct and thus unsustainable; (c) the illegal sales and marketing activities increased the risk of criminal and civil liability; and (d) as a result of the foregoing, Defendants' public statements, including the Company's reported revenue, purported growth drivers, compliance with the FCA and AKS, the effectiveness of its patient access

and reimbursement strategy, and the effectiveness of CVRx's internal controls over financial reporting were materially false and misleading at all relevant times. Additionally, throughout the Class Period, Defendants made materially false and misleading statements regarding the progress of the Company's sales force realignment and the transformation of its commercial organization. Specifically, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) contrary to Defendants' assurances, sales force turnover had not been stabilized and productivity remained materially below expectations because the sales organization required additional training, support, and restructuring; (b) a significant portion of the sales force was inexperienced, required extended training and ramp time, and were not yet capable of generating the productivity to meet revenue projections; and (c) that as a result of the foregoing, Defendants' public statements regarding the progress of the Company's sales force realignment and the transformation of its commercial organization were materially false and misleading at all relevant times.

4. On August 6, 2026, after the market close, CVRx filed a Form 10-Q with the SEC disclosing that on May 14, 2026, the Company "received a civil investigative demand ('CID') from the U.S. Department of Justice in connection with an investigation under the False Claims Act." The Company stated that the "CID requested information and documents regarding an investigation into whether [CVRx] caused the submission of false claims to government health insurance programs by improperly marketing [its] device, offering or paying kickbacks to healthcare providers or providing false information to government health insurance programs."

5. Also on August 6, 2026, CVRx cut its outlook based, in part, on weak sales force productivity. The Company revealed:

> It is important to note that roughly 60% of quota-carrying territory managers have joined us in the last 18 months as we have worked to build the right organization for this next phase of growth. This rapid pace of hiring has strained our onboarding and training processes and the ability of our area sales directors to spend the time necessary to accelerate these new team members up the productivity curve. The scale of the turnover, the slower pace of the territory manager productivity ramp, and the concentration of these new hires in a subset of our regions are the primary factors behind today's guidance update.

6. On this news, CVRx common stock fell $3.55 per share (or 60%), from $5.94 per share on August 6, 2026, to close at $2.39 per share on August 7, 2026, on heavy volume.

7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's shares, Plaintiff and putative class members have suffered significant losses and damages. Plaintiff and putative class members seek damages for redress, reasonable attorneys' fees, injunctive relief, and all other relief this Court deems just and proper.

II. JURISDICTION AND VENUE

8. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5). This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa).

9. Venue is proper in this District under Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b), (c), and (d). Substantial acts in furtherance of the

alleged fraud or the effects of the fraud have occurred in this Judicial District. In addition, during the Class Period the Company's headquarters were located in this District.

10. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mail, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

A. Plaintiff

11. Plaintiff Oklahoma Police Pension and Retirement System ("Oklahoma Police") is a public pension fund and sophisticated institutional investor with headquarters in Oklahoma City, Oklahoma. According to the 2025 Annual Report, Oklahoma Police has net assets of approximately $3.4 billion and has 5,099 active members and 3,298 Retired members. As reflected in its certification submitted herewith as Exhibit 1, Oklahoma Police purchased CVRx common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

B. Corporate Defendant

12. Defendant CVRx is a Delaware corporation with its principal executive offices in Minneapolis, Minnesota. CVRx common stock is listed and traded on the Nasdaq under the symbol "CVRX."

C. Officer Defendants

13. Defendant Kevin Hykes ("Hykes") has served as the Company's President and Chief Executive Officer ("CEO") since February 2024, and as a director on the Board since December 2022.

14. Defendant Nadim Yared ("Yared") served as the Company's President and CEO, and as a director on the Board, from October 2006 to February 2024.

15. Defendant Jared Oasheim ("Oasheim") began serving as the Company's Chief Financial Officer ("CFO") in October 2020. On June 7, 2026, Oasheim "gave notice of his intention to resign from the Company." On September 21, 2026, CVRx announced that John Landry had been appointed CFO and would join the Company on October 12, 2026, the day after the Company files its Form 10-Q for the third quarter of 2026.

16. Defendant Robert John ("John") served as the Company's Chief Revenue Officer ("CRO") from June 2024 to August 2026, when CVRx announced that John would "depart the company."

17. CVRx designates its principal executive officer and two most highly compensated executive officers as its named executive officers ("NEOs"). In 2025, Hykes, John, and Chief Medical Officer Dr. Philip B. Adamson ("Adamson") were identified as NEOs. In 2024, Hykes, Oasheim, John, and Yared were identified as NEOs. In 2023, Yared, Oasheim, and Paul Verrastro ("Verrastro") were identified as NEOs.

18. Defendants Hykes, Yared, Oasheim, and John are referred to herein as the "Officer Defendants."

19. Because of their positions within the Company, the Officer Defendants possessed the power and authority to control the contents of the Company's quarterly reports, press releases, and conference calls with securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. They were provided with copies of and/or contributed to the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions, and their access to material nonpublic information available to them but not to the public, the Officer Defendants knew or recklessly disregarded that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, making their positive representations materially false and misleading. The Officer Defendants are liable as control persons for the false and misleading statements and omissions pleaded herein.

IV. BACKGROUND

A. Barostim's FDA Approval to Treat Heart Failure Symptoms

20. CVRx manufactures, markets, and sells only one device: Barostim. Barostim is an implantable device that delivers electrical pulses to baroreceptors located in the wall of the carotid artery to counteract decreased baroreceptor signaling, which creates an imbalance in the brain's Autonomic Nervous System ("ANS"), resulting in excess neurohormones that cause heart failure with reduced Ejection Fraction ("HFrEF") and other cardiovascular diseases.

21. Heart failure is characterized by the heart's inability to effectively circulate blood throughout the body resulting in insufficient levels of oxygen and nourishment to

various body parts. Heart failure impacts a patient's ability to function and leads to a variety of symptoms such as shortness of breath, extreme fatigue, exercise intolerance, swelling, and fluid retention, and affects a patient's quality of life, both physically and emotionally.

22. HFrEF affects the heart's ability to pump blood efficiently and is characterized by a weakened heart muscle that cannot contract forcefully enough to push enough blood throughout the body. Ejection fraction ("EF") is expressed as a percentage, with a normal EF ranging between 50% and 70%. In individuals with HFrEF, the EF is typically 40% or lower. Patients with HFrEF are typically placed on a treatment progression plan during which they are initially given Guideline-Directed Medical Therapy ("GDMT") to help manage symptoms. Then patients progress to more invasive and costly treatment options involving other implantable devices, with the most severe patients often requiring a pump implanted directly in the heart, called a Left Ventricular Assist Device ("LVAD"), or a heart transplant.

23. In August 2019, Barostim received FDA approval to "improve symptoms" of HFrEF in the U.S. after the Company completed its Baroreflex Activation Therapy for Heart Failure ("BeAT-HF") pivotal trial, which was a multi-center, prospective, randomized, controlled trial, and which met the primary safety and effectiveness endpoints and demonstrated meaningful improvement in the quality of life, both physically and emotionally, for patients suffering from HFrEF.

24. On July 2, 2021, the Company closed its initial public offering ("IPO") of 8,050,000 shares of its common stock at a public offering price of $18.00 per share for net proceeds of approximately $133.3 million.

25. In 2021, CVRx estimated that its "annual market opportunity for HFrEF" was $2.9 billion, including a $1.4 billion initial market opportunity (55,000 HFrEF patients) in the U.S.

26. On February 21, 2023, the Company announced preliminary topline results of the BeAT-HF post-market randomized clinical trial. The post-market follow-up was aimed at demonstrating significant improvements in morbidity and mortality. The BeAT-HF post-market phase of the multi-center, prospective, randomized, controlled trial assessed 323 patients suffering from heart failure with reduced ejection fraction. The patients were randomized into two groups: treatment with Barostim and GDMT versus GDMT alone. The primary endpoint was a composite of cardiovascular mortality and heart failure morbidity (specifically, worsening heart failure events requiring treatment in the hospital or emergency department). The trial ***did not*** reach statistical significance on the primary endpoint.

27. In late 2023, CVRx revised its U.S. annual market opportunity—based on the new long-term safety and effectiveness data of BeAT-HF, commercial experience, and to account for the new reimbursement assignment for Barostim to $2.2 billion, or 76,000 new patients.

B. Sales & Marketing of Barostim

28. CVRx primarily sells Barostim to hospitals through a direct sales organization in the U.S. CVRx states that "sales and marketing efforts are directed at electrophysiologists, [heart failure] specialists, interventional and general cardiologists, and vascular surgeons because they are the primary users of our technology."

29. According to CVRx, growth is driven by increased awareness of Barostim among physicians, patients, and payors and the expansion of the U.S. sales force. In particular, CVRx must expand the size and geographic scope of its U.S. direct sales and marketing organization, including the retention, growth, and development of a substantial number of direct sales personnel. A growing sales force is therefore essential to fuel revenue growth, allowing the Company to expand into new sales territories and new accounts and improve utilization in each territory.

30. The Company states that it is "continuing to actively expand [its] direct sales force and commercial organization in the U.S." and that "direct sales representatives, which [it] refer[s] to as Account Managers [(now known as "Territory Managers")], generally have substantial and applicable medical device experience, specifically in the cardiovascular space, and market our products directly to the approximately 2,500 EPs, 800 [heart failure] specialists, and 20,000 general cardiologists in the U.S."

31. CVRx states that Account Managers "support all aspects of the patient journey, which includes initial diagnosis, surgical support and patient follow-up." In particular, Account Managers focus on: (a) prioritizing high-volume cardiology centers

that are strategically located; and (b) educating and training physicians who have HFrEF patients that may be eligible for Barostim. The Company further states:

> Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with products expected by physicians. Upon completion of the training, sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory.

32. CVRx also employs Field Clinical Specialists who generally have experience in medical device clinical support. Field Clinical Specialists work to ensure that every procedure is done correctly by educating the implanting physicians, including vascular surgeons and EPs, about the technical aspects of Barostim and the implantation procedure.

33. CVRx also states that its "marketing team has a significant amount of relevant expertise and a strong track record of success in the medical device industry." The marketing team utilizes direct communication channels to inform patients about Barostim. The primary method of patient outreach is through "digital social networks." In addition to driving broad awareness and increasing physician and patient education, CVRx states that the marketing team has "developed the in-house resources necessary to obtain prior authorization approval for Barostim procedures and expand reimbursement coverage." CVRx states that expanding the size and geographic scope of U.S. direct sales and marketing organization is critical to generate sustained and increasing product revenue.

C. Third-Party Coverage and Reimbursement

34. Barostim customers bill various third-party payors, such as government agencies, administrative contractors, commercial payors, and integrated managed care organizations for the cost required to treat each patient.

35. Medicare reimbursement levels are important to increasing adoption of Barostim because nearly two-thirds of the target patient population for Barostim is over the age of 65. Accordingly, if third-party payers do not provide adequate coverage and reimbursement for Barostim, the Company's revenue will be negatively impacted.

a. Transitional/Experimental Code Assigned to Barostim

36. Third-party payors generally require physicians and hospitals to identify the service for which they are seeking reimbursement by using Current Procedural Terminology ("CPT") codes, which are created and maintained by the American Medical Association ("AMA").

37. In order to facilitate reimbursement to doctors for services rendered, the AMA developed a system of CPT codes, divided into three categories, which is utilized by insurance companies and federally funded insurance programs to determine eligibility and levels of reimbursement. Federal law, including the False Claims Act, requires medical providers to label services rendered with an appropriate CPT code, to ensure that reimbursement from these sources is legitimately procured. Category III coding is typically applied when there is a lack of clinical data regarding a device which renders it a "new and emerging" technology.

38. For most of the Class Period, implantation of Barostim has been described by CPT code 0266T, a Category III code approved in July 2011 and effective as of January 2012. Hospitals use this code to submit for a system implant payment. The assignment of a Category III, or "T Code" identified the procedure as "investigative" or "experimental" to insurance companies. As a result, most Medicare Advantage and commercial insurance companies have refused to provide reimbursement for Barostim. On January 1, 2026, the AMA replaced the Category III code with a permanent Category I CPT Code.

b. Payment Schedule for Barostim

39. Physician reimbursement under Medicare is generally based on a defined fee schedule, the Physician Fee Schedule, through which payment amounts are determined by the relative values of the professional services rendered. Medicare provides reimbursement to hospitals using Barostim under the hospital outpatient prospective system ("OPPS"), which provides bundled amounts generally intended to reimburse a hospital for all facility costs related to procedures performed in its outpatient setting.

40. The Centers for Medicare and Medicaid Services ("CMS") granted a transitional pass-through ("TPT") payment for the implantation of Barostim in an outpatient setting, which took effect in January 2021 and expired at the end of 2023. A TPT payment is a temporary, incremental payment for new technologies that meet certain qualifications. It allows hospitals to bill for a pass-through of the device cost and can be added to the procedure costs. The surgeon implanting Barostim is paid an additional physician payment under the Medicare Physician Fee Schedule

c. False Claims Act and Anti-Kickback Statute

41. The False Claims Act prohibits, among other things, any person or entity from: (a) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government; or (b) knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil FCA also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the FCA.

42. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully: (a) offering, paying, soliciting, or receiving any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering, or arranging for; or (b) recommending the purchase, lease, or order of any good, facility, item, or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value, including stock, stock options, or the compensation derived through ownership interests.

43. Private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damage

sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program.

44. CVRx's Code of Business Conduct and Ethics states:

> Covered Parties are expected to meet the highest ethical standards and therefore must conduct themselves with appropriate transparency and in compliance with applicable laws, regulations and government guidance. Obeying the law, both in letter and in spirit, is the foundation on which the Company's standards of conduct are built. All Covered Parties must respect and obey the laws of the cities, states and countries in which the Company operates. Although not all Covered Parties are expected to know the details of these laws, it is important to know enough to determine when to seek advice from managers or other appropriate personnel. If a law conflicts with these guidelines, the Covered Party should comply with the law and consult his or her supervisor or the Chief Financial Officer to discuss the situation.
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> Covered Parties should promptly report suspected violations of laws, rules, regulations or the Code to appropriate personnel, including their manager, another supervisor, a member of the Company's Legal or Human Resources department, or a member of the Sr. Leadership team.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS CAUSED SUBSTANTIAL LOSSES TO INVESTORS

45. The Class Period begins on July 25, 2023, when the Company issued a press release announcing the financial results for the second quarter of 2023 ("Q2 2023 Press Release"). The Q2 2023 Press Release stated in relevant part as follows:

> "Our success continues to be driven by our U.S. heart failure business, which saw revenue growth of nearly 120% compared to the prior year quarter. We are proud of our performance, which reflects the continued execution of our commercial strategy and the demand for Barostim in the market," said Nadim Yared, President and Chief Executive Officer of CVRx.
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> HF revenue in the U.S. totaled $8.3 million and $3.8 million for the three months ended June 30, 2023 and 2022, respectively. The increases were

> primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts and increased physician and patient awareness of Barostim.[1]

46. On August 3, 2023, the Company issued its quarterly report on Form 10-Q for the second quarter 2023 with the SEC ("Q2 2023 Form 10-Q"). The Q2 2023 Form 10-Q was signed by Defendants Yared and Oasheim.

47. The Q2 2023 Form 10-Q stated, in relevant part, as follows:

> Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> * * *
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients, and payors and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> HF revenue in the U.S. totaled $8.3 million and $3.8 million for the three months ended June 30, 2023 and 2022, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

48. The Q2 2023 Form 10-Q included certifications signed by Defendants Yared and Oasheim pursuant to the Sarbanes-Oxley Act of 2002 ("SOX Certifications"). The SOX Certifications stated:

[1] Heart Failure is also referred to as "HR" herein.

1. I have reviewed this quarterly report on Form 10-Q of CVRx, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal controls over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected,

> or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
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> 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
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> (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
>
> (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

49. Defendants Yared and Oasheim signed identical SOX Certifications in connection with the Company's Form 10-Qs filed on August 3, 2023, and October 31, 2023, and Form 10-K filed on February 9, 2024. Defendants Hykes and Oasheim signed identical SOX Certifications in connection with the Company's Form 10-Qs filed on May 10, 2024, August 2, 2024, November 1, 2024, May 9, 2025, August 5, 2025, November 6, 2025, and May 12, 2025, and Form 10-Ks filed on February 18, 2025, and February 13, 2026.

50. On October 26, 2023, the Company issued a press release announcing the financial results for the third quarter of 2023 ("Q3 2023 Press Release"). The Q3 2023 Press Release stated, in relevant part, as follows:

> "We're pleased with the growth trajectory of our business, which has continued to exceed our expectations throughout 2023. The impressive performance of our U.S. heart failure business has been driven by the expansion of our commercial team and the increased positive impacts of our marketing efforts," said Nadim Yared, President and Chief Executive Officer of CVRx.

* * *

> HF revenue in the U.S. totaled $9.4 million and $4.9 million for the three months ended September 30, 2023 and 2022, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

51. On October 26, 2023, CVRx held a Q3 2023 Earnings Call ("Q3 2023 Call"). Defendants Yared and Oasheim participated in the Q3 2023 Call.

52. During the Q3 2023 Call, Yared stated:

> Worldwide revenue was $10.5 million, a 70% increase over the third quarter of 2022. This was a direct result of execution within our US Heart Failure business, which grew by 92% over the prior year. These results were achieved through the increased utilization of Barostim among our existing customer base, the continued addition of new active implanting centers, the measured expansion of new sales territories in the US and increased awareness among physicians and patients.

53. On October 31, 2023, the Company issued its quarterly report on Form 10-Q for the third quarter 2023 with the SEC ("Q3 2023 Form 10-Q"). The Q3 2023 Form 10-Q was signed by Defendants Yared and Oasheim.

54. The Q3 2023 Form 10-Q stated, in relevant part, as follows:

> Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.

* * *

> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients, and payors and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

* * *

> HF revenue in the U.S. totaled $9.4 million and $4.9 million for the three months ended September 30, 2023 and 2022, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

55. On January 25, 2024, the Company issued a press release announcing the financial results for the fourth quarter and full year of 2023 ("FY 2023 Press Release"). The FY 2023 Press Release stated in relevant part as follows:

> "As we reflect on the accomplishments of 2023, it has been a great year for CVRx. We are proud to have sustained the momentum in driving the adoption and utilization of Barostim, resulting in a 97% annual increase in U.S. heart failure revenue," said Nadim Yared, President and CEO of CVRx.

* * *

> HF revenue in the U.S. totaled $10.2 million and $6.0 million for the three months ended December 31, 2023 and 2022, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

56. On February 9, 2024, the Company issued its annual report on Form 10-K for the fiscal year ended December 31, 2023 and fourth quarter 2023 with the SEC ("FY 2023 Form 10-K"). The FY 2023 Form 10-K was signed by Defendants Yared, Oasheim, and Hykes.

57. The FY 2023 Form 10-K stated, in relevant part, as follows:

> We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany and through distributors in Austria, Spain, Italy, the Nordic region and other European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on electrophysiologists ("EPs"), HF specialists, interventional cardiologists, general cardiologists and vascular surgeons. We are prioritizing our sales and marketing efforts on high volume cardiology centers that are

strategically located and on educating and training physicians. We support all aspects of the patient journey, which includes initial diagnosis, surgical support and patient follow-up. We also highlight our compelling clinical benefits and value proposition to build awareness and adoption among physicians through targeted key opinion leader ("KOL") development, referral network education and direct-to-consumer marketing. We utilize direct communication channels to inform and educate patients about Barostim Therapy and utilize a qualification process to aid in the identification of the appropriate patients for our therapy. In the U.S., Barostim is reimbursed by the Centers for Medicare and Medicaid Services ("CMS") across all regions. We assist with reimbursement approvals, if required. We plan to continue actively expanding our direct sales force and commercial organization in the U.S., which is where we expect to focus most of our sales and marketing efforts in the near-term.

* * *

We will continue to leverage our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. We believe our market access team is highly effective in obtaining prior authorizations, including navigating the appeals process. We believe that we will continue to benefit from this efficient prior authorization process in the near-and-long-term by expanding on our positive coverage policies with commercial payors.

* * *

If third-party payors do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted.

Medicare reimbursement levels are important to increasing adoption of Barostim because nearly two-thirds of the target patient population for Barostim is over the age of 65. In the 2024 OPPS final rule issued in November 2023, Barostim was reassigned to New Technology APC 1580, which carries an average payment amount of $45,000. The new payment took effect January 1, 2024. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business. From time to time, physicians and hospitals have in the past experienced, and others may experience, delays in Medicare reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

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The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in inappropriate promotion.

Barostim has been indicated for the improvement of symptoms of HFrEF by the FDA and the treatment of HFrEF in the EEA. We may only promote or market Barostim for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as "off-label uses."

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Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payors, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

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HF revenue in the U.S. totaled $34.6 million and $17.6 million for the years ended December 31, 2023 and 2022, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim. Total HF revenue units in the U.S. totaled 1,123 and 587 for the years ended December 31, 2023 and 2022, respectively.

58. Concerning compliance with laws and regulations, the FY 2023 Form 10-K stated, in relevant part, as follows:

We are subject to certain federal, state and foreign fraud and abuse laws, transparency and privacy and security laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We are subject to privacy and security regulation related to patient, customer, employee and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the U.S., the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

* * *

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

59. On April 30, 2024, the Company issued a press release announcing the financial results for the first quarter of 2024 ("Q1 2024 Press Release"). The Q1 2024 Press Release stated, in relevant part, as follows:

> "We had a solid first quarter, which was offset by some commercial execution challenges in our U.S. Heart Failure business during our recent management transition in February. We are taking steps to address these challenges, including a change in sales leadership, which we are announcing today. I've also begun the process of broadening our leadership team and intensifying our efforts on therapy awareness, clinical evidence, and patient access, which will be important in order to scale the business to address the tremendous opportunity in front of us," said Kevin Hykes, President and Chief Executive Officer of CVRx.
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> HF revenue in the U.S. totaled $9.7 million and $6.8 million for the three months ended March 31, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

60. On April 30, 2024, CVRx held a Q1 2024 Earnings Call ("Q1 2024 Call"). Defendants Hykes and Oasheim participated in the Q1 2024 Call.

61. During the Q1 2024 Call, Hykes stated:

> The lower than anticipated revenue was due primarily to the performance of our US heart failure business, where there was some disruption within our sales organization at the time of the CEO transition, which led to decreased productivity and some sales force turnover, while stabilizing the team and returning active territories to full productivity will take some time. I'm encouraged that some of the early actions we have taken have led to solid performance in our US heart failure business in March.
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> As noted, our first quarter revenue performance was below expectations as a high growth commercial stage company, the effectiveness of our sales organization is critical. Based on my assessment of our sales team and the disruption that we saw in Q1, I've determined that a change in leadership is

> needed to maximize the opportunity in front of us. As a result, our Senior Vice President of sales will be departing the company. We have initiated a thorough search to identify a candidate who can scale this business to reach its full potential.

62. On May 10, 2024, the Company issued its quarterly report on Form 10-Q for the first quarter 2024 with the SEC ("Q1 2024 Form 10-Q"). The Q1 2024 Form 10-Q was signed by Defendants Hykes and Oasheim.

63. The Q1 2024 Form 10-Q stated, in relevant part, as follows:

> Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> HF revenue in the U.S. totaled $9.7 million and $6.8 million for the three months ended March 31, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim. These increases were partially offset by decreased productivity in February due primarily to turnover within the sales organization. We implemented actions to address these challenges in our U.S. Heart Failure business to rebuild these territories, resulting in stronger performance in March.

64. On June 5, 2024, CVRx attended the William Blair Growth Stock Conference ("William Blair Conference"). Defendants Hykes and Oasheim participated in the William Blair Conference.

65. During the William Blair Conference, Hykes commented on the Q1 sales force issue, stating:

> As many of you know, we saw higher-than-expected turnover in Q1, and as a result experienced some disruption in our selling efforts. I'm pleased to mention that the reaction from the sales team to the changes we've made since then has been very positive, both to the revised compensation plan, to the change in their national sales leader and the reception of our new interim sales leader, who was, prior to this, our Chief Marketing Officer. As a result, we have seen zero turnover in Q2 in our sales force, which leads me to believe that we have stabilized the team and are gaining our momentum back. I'm also pleased that we're continuing to attract very impressive candidates who are applying for work at CVRx and we had an impressive Q1 recruiting class that we're pleased with.
>
> So, based on the strength of the business in April and May, and in particular the stability we're seeing within the sales team, we are choosing to reaffirm both our Q2 and 2024 guidance as of today. We continue to believe that we will deliver revenue within the range of our guidance of $11.3 million to $12.3 million for the second quarter.

66. Regarding patient access and reimbursement, Hykes stated:

> The third area where we will focus is to accelerate patient access to the therapy. Our reimbursement efforts will continue to focus on leveraging this long-term data to improve private and public payer coverage, to establish and work towards permanent codes for the therapy and procedure and to maintain appropriate payment for the procedure in both the inpatient and outpatient settings.
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> On the right, you see the payer mix of Barostim-eligible patients. 67% of which are Medicare patients and about 20% of which are commercial patients. With the current penetration of Medicare Advantage plans, that means that roughly half of all Barostim patients will require a prior authorization, at least in the near-term, to receive our therapy. And for that reason, we are increasing our support and focus and investment in our

> internal prior authorization support capabilities as part of the Barostim Connect Program.
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> But reimbursement, it's a necessary evil with any novel therapy. It's unavoidable. This company is actually doing better than most that I've been involved with at this stage.

67. On July 29, 2024, the Company issued a press release announcing the financial results for the second quarter of 2024 ("Q2 2024 Press Release"). The Q2 2024 Press Release stated, in relevant part, as follows:

> "We are pleased with our solid second quarter results, driven by another record quarter in our U.S. Heart Failure business. We remain extremely optimistic about the Barostim technology and our market opportunity. Our recent leadership appointments have significantly bolstered our executive team, positioning us well to address key market development priorities," said Kevin Hykes, President and Chief Executive Officer of CVRx.
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> HF revenue in the U.S. totaled $10.5 million and $8.3 million for the three months ended June 30, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

68. On July 29, 2024, CVRx held a Q2 2024 Earnings Call ("Q2 2024 Call"). Defendants Hykes and Oasheim participated in the Q2 2024 Call.

69. During the Q2 2024 Call, Hykes was asked by an analyst, "In terms of the sales force, has that fully been stabilized and it's all adds here or since the last call, did you see more turnover?" Hykes responded that sales force problems were stabilized and contained to the first quarter, stating, as follows:

> Thanks to Paul Verrastro stepping in, and without missing a beat, he was quickly able to stabilize our sales team and to limit the disruption largely to

> the first quarter. As I mentioned at a public event in early June, we had turnover down to zero in the early part of the quarter. And while there were a few more heads that left, turnover is still well below what we would have expected for a company of our size and stage. So we're pleased that what we're hearing from the team, they're energized and excited about their new leader who brings 25 years' experience building teams from scratch and deep, deep relationships. So, I feel really good about the morale within that team and the strong sense of momentum.
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> [W]e've been really pleased with both the Q1 and Q2 classes of reps. These are, I think, the highest quality and importantly most appropriately experienced reps we've yet hired. And as I mentioned, we're kind of going through a transition here from the early chapter where you try a whole bunch of different things, including a bunch of different rep profiles, and you start to understand what really works well. And I think we have gotten better and better at choosing reps who don't just have a rolodex necessarily or don't just happen to know cardiac anatomy, but who have built programs and who've worked in a market development environment and launched a novel therapy like this with all that comes with that.

70. During the Q2 2024 Call, Oasheim commented on the sales force, stating:

> [W]e had some – people have taken over territories in the first quarter and getting them up to speed. I think the thing we'd like to highlight is really the reps that we are hiring here in 2024 are really high-quality individuals, getting up to speed and getting through their training programs on a – at a really quick pace to the point where they can get out in the field and start making a difference here as we get to the back half of this year.

71. During the Q2 2024 Call, Hykes commented on patient access and reimbursement, stating:

> As it relates to supporting Medicare Advantage or commercial prior authorizations for that matter, we have a very robust in-house prior authorization function. That's part of the Barostim Connect program that has had, I think, surprising success both with commercial payers and with Medicare Advantage supporting and appealing and ultimately winning patient prior authorization requests. So, I think we're pleased with what we're seeing. We're bringing newfound experience and engagement to bear on both those sides, as well as our interactions with Medicare and the MACs. So we're pleased at what we're seeing.

72. During the Q2 2024 Call, Hykes was asked by an analyst about an "inpatient opportunity" with increased reimbursement rates:

> ANALYST: [T]he next step and Kevin, you're kind of introducing this inpatient opportunity. If the proposed outpatient rule comes back and they're really saying, no, we're sticking with this $31,000 reimbursement rate, is there an opportunity to shift quickly to the inpatient side and not see as much pricing pressure as a result of that? Or is that just far too aggressive? I don't know, mechanistically, how easy it would be to do something like that.
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> HYKES: The short answer is we cannot and will not influence site of service. So we cannot ourselves shift or even wink or nod where physicians might treat patients. Our goal is to make sure that the therapy is in the hospitals and physicians themselves are appropriately reimbursed whether they choose to do it in the inpatient setting or the outpatient setting. It's a little paradoxical that the inpatient rule would have us moving from $23,000 up to $45,000 or $46,000 at the same time that there's this noise on the OPPS side. But you we would support physicians in their decision making regardless where they would choose to treat a patient. If that results in a shift in the mix, we're ready to support it. But certainly we wouldn't want to influence that.

73. On August 2, 2024, the Company issued its quarterly report on Form 10-Q for the second quarter 2024 with the SEC ("Q2 2024 Form 10-Q"). The Q2 2024 Form 10-Q was signed by Defendants Hykes and Oasheim.

74. The Q2 2024 Form 10-Q stated, in relevant part, as follows:

> Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

75. On August 14, 2024, CVRx attended the CG Growth Conference. Defendants Hykes and Oasheim participated in the CG Growth Conference.

76. During the CG Growth Conference, Hykes stated:

> As far as going back to Q1, what we saw was a little bit higher than expected turnover in that sales force for a variety of factors. But since then, we've been able to bring on a lot of really strong candidates in the first half of the year that we believe we'll be able to pay off here in the second half.

77. On October 29, 2024, the Company issued a press release announcing the financial results for the third quarter of 2024 ("Q3 2024 Press Release"). The Q3 2024 Press Release stated, in relevant part, as follows:

> "We're thrilled with our continued strong performance in the third quarter, which reflects the growing adoption of Barostim therapy and the dedication of our team," said Kevin Hykes, President and Chief Executive Officer of CVRx. "The recent favorable news regarding inpatient reimbursement and the Category 1 code, coupled with new long-term data demonstrating Barostim's durable quality of life benefits, strengthens our position in the market. We remain focused on improving patient access, increasing education and awareness, and expanding our clinical evidence base. These developments, along with our strengthened leadership team and stabilized sales force reinforce our confidence in Barostim's potential to become standard of care for patients suffering from the debilitating symptoms of heart failure."
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> HF revenue in the *U.S.* totaled $12.2 million and $9.4 million for the three months ended September 30, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the *U.S.* HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

78. On October 29, 2024, CVRx held a Q3 2024 Earnings Call ("Q3 2024 Call"). Defendants Hykes and Oasheim participated in the Q3 2024 Call.

79. During the Q3 2024 Call, Hykes commented on the sales force, stating:

> In the third quarter, we continue to build on the momentum that we established earlier this year. Our strengthened leadership team and stabilized sales force have been instrumental in driving our market development priorities and advancing the adoption of Barostim therapy.
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> I'm particularly pleased with the talent that we had on the team to begin with and the new team members that Robert John is bringing into our organization. Not surprisingly, we're refining some of the profile of who we look for, for these roles. And one of the key components of building deep adoption and sustainable programs is hiring sales representatives that understand how to build these programs. It's a specialized skill. It's not about slightly better mousetrap or a head-to-head competitive play. This is about building a coalition of support in a center for a new therapy or technology.
>
> So we're thrilled with what we're seeing. I would say our turnover is exactly where we would expect it to be, and we are getting better and better at onboarding these new sales reps, especially those that understand the program growth component, onboarding them more effectively and more rapidly than we've seen in the past. So, I think we'll continue to track their contributions going forward. I wouldn't expect a dramatic change in Q4 necessarily in their productivity, but we're pleased at what we're seeing and that's what's leading to our sense of confidence here as we go into the quarter.

80. During the Q3 2024 Call, Hykes commented on CVRx's patient access efforts, stating:

> Our second initiative focuses on increasing education and awareness among referrers and patients. We've expanded our outreach efforts beyond heart failure specialists to include general cardiologists and their advanced practice providers. Our Barostim Connect program continues to be effective in providing education and prior authorization support to prospective patients.

81. During the Q3 2024 Call, an analyst asked Hykes about the performance of the new sales force employees, inquiring as follows:

> Then maybe on the sales force; lot of new adds, obviously, earlier this year. Kind of how's retention been there? And then, second, are you kind of happy with their productivity as far as how quickly they've been able to ramp?

> Were they productive as you would have expected them to be in Q3? And then kind of what are your kind of expectations from a sales rep productivity standpoint in Q4? Thanks.

82. In response, Hykes reassured:

> So, I would say we're pleased – I'm particularly pleased with the talent that we had on the team to begin with and the new team members that Robert John is bringing into our organization. Not surprisingly, we're refining some of the profile of who we look for, for these roles. And one of the key components of building deep adoption and sustainable programs is hiring sales representatives that understand how to build these programs. It's a specialized skill. It's not about slightly better mousetrap or a head-to-head competitive play. This is about building a coalition of support in a center for a new therapy or technology.
>
> So we're thrilled with what we're seeing. I would say our turnover is exactly where we would expect it to be, and we are getting better and better at onboarding these new sales reps, especially those that understand the program growth component, onboarding them more effectively and more rapidly than we've seen in the past. So, I think we'll continue to track their contributions going forward. I wouldn't expect a dramatic change in Q4 necessarily in their productivity, but we're pleased at what we're seeing and that's what's leading to our sense of confidence here as we go into the quarter.

83. On November 11, 2024, the Company issued its quarterly report on Form 10-Q for the third quarter 2024 with the SEC ("Q3 2024 Form 10-Q"). The Q3 2024 Form 10-Q was signed by Defendants Hykes and Oasheim.

84. The Q3 2024 Form 10-Q stated, in relevant part, as follows:

> Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded

> labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> HF revenue in the U.S. totaled $12.2 million and $9.4 million for the three months ended September 30, 2024 and 2023, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

85. On December 4, 2024, CVRx attended the Piper Sandler Healthcare Conference ("Piper Sandler 2024 Conference"). Defendants Hykes and Oasheim participated in the Piper Sandler 2024 Conference.

86. On January 12, 2025, the Company issued a press release announcing preliminary financial results for the full year and fourth quarter of 2024 ("Preliminary FY 2024 Press Release"). The Preliminary FY 2024 Press Release stated in relevant part as follows:

> "We ended 2024 with a strong fourth quarter, highlighted by 41% growth in U.S. heart failure revenue, as we continued to see the benefits of the successful execution of our commercial strategy as well as our focus on increasing education and awareness, expanding our clinical evidence base, and improving patient access," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Beyond the strength of our revenue performance, we continue to deliver increasing operating leverage as a result of our prudent capital deployment strategy."
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> "We are inspired by the exciting prospects of 2025. Having successfully navigated a number of critical reimbursement milestones during 2024, in combination with the positive utilization and adoption momentum we built throughout the year, we believe we are very well positioned to continue to drive strong, sustainable, cost-efficient topline growth in the coming year as Barostim advances toward the standard of care for patients suffering from the debilitating symptoms of heart failure."

87. On February 4, 2025, the Company issued a press release announcing financial results for the full year and fourth quarter of 2024 ("FY 2024 Press Release"). The FY 2024 Press Release stated, in relevant part, as follows:

> "We capped off a very strong 2024 with a solid fourth quarter, which included 41% growth in U.S. heart failure revenue as well the successful achievement of multiple critical reimbursement milestones," said Kevin Hykes, President and CEO of CVRx. "As we look to 2025, we are focused on three key strategic priorities to drive Barostim toward becoming the standard of care – building a world-class sales organization, supporting the development of sustainable Barostim programs to drive deeper utilization, and addressing barriers to adoption. With the organization-wide success we saw in 2024, in combination with our key priorities for 2025, we are well-positioned to drive the continued adoption of Barostim therapy."
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> HF revenue in the U.S. totaled $14.3 million and $10.2 million for the three months ended December 31, 2024 and 2023, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

88. On February 4, 2025, CVRx held a FY 2024 Earnings Call ("FY 2024 Call"). Defendants Hykes and Oasheim participated in the FY 2024 Call.

89. During the FY 2024 Call, Hykes touted how CVRx had "stabilized the sales organization," stating:

> Throughout 2024, we made significant progress building a strong foundation to support future growth. After some disruption in the sales force early in the year, we stabilized the sales organization, brought in new commercial leadership and made significant steps towards building out a world-class sales team. This team is now implementing a go-to-market strategy focused on driving deeper penetration within new and existing accounts by implementing a disciplined targeting strategy and a program focused selling approach. The team's execution, along with our expansion into 48 territories in the United States, allowed us to end the year with 223 active implanting centers, up from 178 at the end of 2023.

> Beyond the build out and optimization of our commercial team, we focused on addressing key barriers to adoption by improving patient access to the therapy, increasing education and awareness among physicians, advanced practice providers and patients, and developing a more robust portfolio of clinical evidence.
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> For 2025, we're focused on three key strategic priorities. First, we're building a world-class sales organization focused on developing sustainable Barostim program with deep therapy adoption. This includes recruiting sales representatives with strong therapy development backgrounds, strengthening our training and onboarding programs, and aligning our incentives to support program-oriented sales processes.
>
> To support this evolution, we're implementing a new compensation structure that rewards the key elements of a successful program, including consistency of implants and the development of multiple physician champions at each center.

90. During the Q4 2024 Call, Hykes touted its patient access efforts, stating:

> Our second adoption related initiative focused on increasing awareness among referrers and patients regarding the appropriate role for Barostim therapy in the heart failure treatment continuum. We expanded our therapy educational programs, including launching our comprehensive ASCEND program for heart failure fellows and piloted programs for referral physicians and affiliated practice providers referred to as APPs. Additionally, our Barostim Connect program continued to be highly effective in providing education and prior authorization support to prospective patients.

91. On February 18, 2025, the Company issued its annual report on Form 10-K for the fiscal year ended December 31, 2024 and fourth quarter 2024 with the SEC ("FY 2024 Form 10-K"). The FY 2024 Form 10-K was signed by Defendants Yared and Oasheim.

92. The FY 2024 Form 10-K stated, in relevant part, as follows:

> We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany and through distributors in Austria, Spain, Italy, the Nordic region, and other European countries. Our global sales and marketing

team engages in sales efforts and promotional activities focused on electrophysiologists ("EPs"), HF specialists, interventional cardiologists, general cardiologists, and vascular surgeons. We are prioritizing our sales and marketing efforts on high volume cardiology centers that are strategically located and on educating and training physicians. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. We also highlight our compelling clinical benefits and value proposition to build awareness and adoption among physicians through targeted key opinion leader ("KOL") development, referral network education and direct-to-consumer marketing. We utilize direct communication channels to inform and educate patients about Barostim Therapy and utilize a qualification process to aid in the identification of the appropriate patients for our therapy. In the U.S., Barostim is reimbursed by the Centers for Medicare and Medicaid Services ("CMS") across all regions. We assist with reimbursement approvals, if required. We plan to continue actively expanding our direct sales force and commercial organization in the U.S., which is where we expect to focus most of our sales and marketing efforts in the near-term.

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We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany, and through distributors in Austria, Spain, Italy, the Nordic region, and other European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on EPs, HF specialists, interventional and general cardiologists, and vascular surgeons. We are continuing to actively expand our direct sales force and commercial organization in the U.S.

Our direct sales representatives, which we refer to as Account Managers, generally have substantial and applicable medical device experience, specifically in the cardiovascular space, and market our products directly to the approximately 2,500 EPs, 800 HF specialists and 20,000 general cardiologists in the U.S. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. Our Account Managers are focused on prioritizing high volume cardiology centers that are strategically located and on educating and training physicians who have strong connectivity to the HFrEF patient population that may be eligible for our therapy. We also employ Field Clinical Specialists who generally have experience in medical device clinical support. Our Field Clinical Specialists work to ensure that every procedure is done correctly by educating the implanting physicians, including vascular surgeons and EPs, about the technical aspects of Barostim and the implantation procedure.

Similar to our direct sales team, our marketing team has a significant amount of relevant expertise and a strong track record of success in the medical device industry. Our marketing organization is focused on building physician awareness through targeted KOL development, referral network education and direct-to-consumer marketing.

In terms of patient education, we utilize direct communication channels to inform patients about Barostim Therapy and to enable them to connect with sites that offer Barostim. Our primary method of patient outreach is through digital social networks. We use a qualification process to aid in the identification of the appropriate patients for our therapy. The objective of this outreach is to inform potential patients about our education webinars and website, where they can find a wealth of information on HFrEF and the purpose and benefits of Barostim Therapy, based on our approved labeling.

In addition to driving broad awareness and increasing physician and patient education, our marketing team has developed the in-house resources necessary to obtain prior authorization approval for Barostim procedures and expand reimbursement coverage.

* * *

We will continue to leverage our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. We believe our market access team is highly effective in obtaining prior authorizations, including navigating the appeals process. We believe that we will continue to benefit from this efficient prior authorization process in the near-and-long-term by expanding on our positive coverage policies with commercial payers.

* * *

We have limited commercial sales experience marketing and selling Barostim, and if we are unable to continue to maintain and grow sales and marketing capabilities, we will be unable to generate sustained and increasing product revenue.

In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our U.S. direct sales and marketing organization. In order to increase our sales and marketing efforts, we will need to continue to retain, grow and develop a substantial number of direct sales personnel, which is a significant investment. There is significant competition for sales personnel experienced in relevant medical device sales.

Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect, and our financial performance will suffer. Because the competition for direct medical sales personnel is high, we cannot be certain we will be able to hire and retain additional sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating anticipated revenue. Any of these risks may adversely affect our business.

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If we fail to properly manage our growth effectively, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

* * *

If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel.

Transitions in executive leadership can adversely affect relationships with our customers, suppliers, and employees, make it difficult to attract and retain talent, and disrupt execution of our strategy, sales growth, and our efforts to enhance our operations. Additionally, such transitions can require significant payments to recruit and attract qualified employees to join our company and may involve severance payments to certain departing employees. Changes in key management positions may temporarily affect

our financial performance and results of operations as the new management becomes familiar with our business and establishes their team dynamic…. Accordingly, our future financial performance will depend on our ability to attract, motivate, integrate, and retain our senior management and employees, and effectively manage this period of transition under our new leadership.

* * *

If third-party payers do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted.

Medicare reimbursement levels are important to increasing adoption of Barostim and establishing Barostim as the standard of care because nearly two-thirds of the target patient population for Barostim is over the age of 65…. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business, or establish Barostim as the standard of care. From time to time, physicians and hospitals have in the past experienced, and others may experience, denials in Medicare and commercial reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

* * *

The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in inappropriate promotion.

Barostim has been indicated for the improvement of symptoms of HFrEF by the FDA and the treatment of HFrEF in the EEA. We may only promote or market Barostim for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as "off-label uses."

* * *

Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement

changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

* * *

HF revenue in the U.S. totaled $46.8 million and $34.6 million for the years ended December 31, 2024 and 2023, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

93. Concerning compliance with laws and regulations, the FY 2024 Form 10-K stated, in relevant part, as follows:

We are subject to certain federal, state, and foreign fraud and abuse laws, transparency and privacy and security laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We are subject to privacy and security regulation related to patient, customer, employee, and other third-party information by both the federal government and the states and foreign jurisdictions in which we conduct our business. In the U.S., the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

> - federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;
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> These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians, or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

94. The statements in paragraphs 45 to 93 were false and misleading when made, and omitted to state material facts necessary to make the statements not misleading. Specifically, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) to induce sales growth, CVRx and/or its employees were engaged in illegal and unsustainable sales practices, including improperly marketing Barostim, offering or paying kickbacks, and providing false information to government health insurance program which violated the FCA and the AKS ; (b) CVRx's revenues were in part the product of such unlawful conduct and thus unsustainable; (c) the illegal sales and marketing activities increased the risk of a criminal and civil liability; and (d) that as a result of the foregoing, Defendants' public statements, including the Company's reported revenue, the purported growth drivers, compliance with the FCA and AKS, the

effectiveness of its patient access and reimbursement strategy, and the effectiveness of CVRx's internal controls over financial reporting were materially false and misleading at all relevant times. Additionally, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) sales force turnover had not been stabilized and productivity remained materially below expectations because the sales organization required additional training, support, and restructuring; (b) a significant portion of the sales force were inexperienced, required extended training and ramp time, and were not yet capable of generating the productivity to meet revenue projections; and (c) that as a result of the foregoing, Defendants' public statements regarding the progress of the Company's sales force realignment and the transformation of its commercial organization were materially false and misleading at all relevant times.

95. On April 7, 2025, after the market close, the Company issued a press release announcing preliminary financial results for the first quarter of 2025 ("Preliminary Q1 2025 Press Release"). The Preliminary Q1 2025 Press Release revealed sales force problems and stated, in relevant part, as follows:

> "While we continue to make significant progress in driving adoption of Barostim, first quarter revenue fell short of our expectations," said Kevin Hykes, President and Chief Executive Officer of CVRx. "A core element of the commercial strategy initiated last year has been to build a world-class sales organization. As part of this effort, we brought in a number of new high-quality sales representatives in the back half of 2024 and the first quarter of 2025. We are thrilled with the level of talent we have attracted to strengthen our team, but many of these newer sales representatives are still in the early stages of territory development. In addition, the first quarter of 2025 was impacted by seasonal softness, as patients and customers schedule procedures around insurance coverage and deductibles. We did not fully anticipate this impact because past first quarter events, including COVID

> spikes, material clinical data releases, and management changes, likely obscured the magnitude of first-quarter seasonality."
>
> "Despite the disappointing revenue performance in the quarter, we remain confident in our ability to drive growth in Barostim adoption. We continue to believe that our strategic focus on driving deep penetration within high-potential accounts will unlock higher future growth. We look forward to providing further information on the earnings call with the release of our full first quarter results in early May."

96. On this news, shares fell from a closing price of $11.54 per share on April 7, 2025, to $6.20 per share on April 8, 2025, a decline of $5.34 per share or 46%, on heavy volume.

97. In an April 8, 2025 report, a William Blair analyst commented:

> After the markets closed on April 7, CVRx announced preliminary first-quarter sales of $12.3 million (15% growth), which were over $2 million (16%) below our estimate and the low end of first-quarter guidance of $14.5 million. Management attributed the miss to two factors: greater seasonality than expected (suggesting the procedure is more elective than initially anticipated in its initial years of launch) and company-initiated salesforce turnover. Though the company did not disclose the extent of the contribution from either factor, we believe the latter likely had the bigger impact of the two.

98. On May 8, 2025, after the close, the Company issued a press release announcing preliminary financial results for the first quarter of 2025 ("Q1 2025 Press Release"). The Q1 2025 Press Release stated, in relevant part, as follows:

> "We're encouraged about the momentum building in our business as we move into the second quarter," said Kevin Hykes, President and Chief Executive Officer of CVRx. "While revenue growth in the first quarter didn't meet our expectations, we added a significant number of new sales representatives, and are very pleased with the talent we have attracted to the organization. As these reps are still in the early stages of building their territories, we expect their contributions to grow as the year progresses. We continue to support these commercial initiatives by advancing our growing body of clinical evidence, highlighted by our recently published

> hospitalization data from the Premier Healthcare Database, which further reinforced Barostim's value proposition in the treatment of heart failure patients."
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> HF revenue in the U.S. totaled $11.1 million and $9.7 million for the three months ended March 31, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 353 and 319 for the three months ended March 31, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

99. On May 8, 2025, CVRx held a Q1 2025 Earnings Call ("Q1 2025 Call"). Defendants Hykes and Oasheim participated in the Q1 2024 Call.

100. During the Q1 2025 Call, the Company revealed more information about the severity of sales force productivity problems. In particular, Hykes stated:

> While we continue to make significant progress in driving Barostim to become the standard of care for heart failure, our revenue performance fell short of expectations due to two factors.
>
> The first and primary factor was our sales force realignment. Following the change in sales leadership in mid-2024, our new Chief Revenue Officer utilized the back half of the year to evaluate the team and the company's commercial effectiveness, concluding that we needed to strengthen our sales team. Ultimately, the depth of these necessary changes was more significant than initially anticipated and resulted in 25% of our current territory managers being hired between December and March.
>
> As with any organizational transition of this magnitude, the productivity ramp for new hires will vary significantly depending on the sales rep's background and experience, as well as whether the new hire is entering a new territory or an existing territory with established accounts. These transitions can also cause disruption at the account level, especially in dabbler accounts that have a high degree of relationship dependence, an impact that was more difficult to manage in Q1 than was anticipated.

101. On this news, shares fell from a closing price of $7.78 per share on May 8, 2025, to $4.77 per share on May 9, 2025, a decline of $3.01 per share or 39%, on heavy volume.

102. In a May 8, 2025 report, Canaccord Genuity Capital Markets stated, "[d]iscussions with management made it clear that the salesforce transition is not fully complete, and that the expected ramp in productivity – along with the more narrowed account criteria that CVRX is implementing – likely won't happen near-term."

103. In a May 9, 2025 report, J.P. Morgan commented, "CVRx reported a miss in 1Q with sales of $12.3M below the Street at $13.3M as the planned salesforce reorganization led to greater than expected turnover and account disruption. This resulted in lowered guidance of $55-58M from $63-65M."

104. Despite the revelation of serious sales-force productivity issues, during the Q1 2025 Call, Hykes reassured that these were merely "short-term headwinds," stating as follows:

> We're thrilled with the quality of the talent that we've been able to attract, and we expect to see productivity improvement and account stabilization throughout the year, as these representatives gain traction and experience.
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> In summary, we remain confident in our strategy and the fundamental strength of our business. We have a clear path forward with our strategic priorities, a talented and increasingly experienced sales force, and compelling clinical evidence demonstrating the value of Barostim, including significant reductions in hospitalizations. As our newer sales representatives gain traction in their territories and with continued execution of our program-focused selling strategy, we expect to see a return to higher growth.
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> * * *

> While the realignment and strengthening of our sales force has created some short-term headwinds, we're already seeing positive signs that validate our approach. We believe our focus on attracting high-quality sales representatives with strong therapy development backgrounds will pay dividends, as these representatives move through their productivity curves and gain more experience in their territories. Our strategy to focus on driving deep penetration within high-volume accounts is showing encouraging preliminary results at the account level. These centers have the patient volumes, infrastructure and clinical expertise necessary to develop sustainable Barostim programs.

105. On May 9, 2025, the Company issued its quarterly report on Form 10-Q for the first quarter 2025 with the SEC ("Q1 2025 Form 10-Q"). The Q1 2025 Form 10-Q was signed by Defendants Hykes and Oasheim.

106. The Q1 2025 Form 10-Q stated, in relevant part, as follows:

> The costs for the device and implantation procedure are reimbursed through various third-party payers, such as government agencies and commercial payers. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services while simultaneously developing processes to engage commercial payers. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be adjudicated on a claim-by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking

> expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> HF revenue in the U.S. totaled $11.1 million and $9.7 million for the three months ended March 31, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 353 and 319 for the three months ended March 31, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

107. On August 4, 2025, the Company issued a press release announcing financial results for the second quarter of 2025 ("Q2 2025 Press Release"). The Q2 2025 Press Release stated, in relevant part, as follows:

> "We delivered solid second quarter results and continued to build momentum across our business," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our sales force transformation is gaining traction, and we're building sustainable Barostim programs with high potential centers. We continue to make progress on multiple fronts by advancing our clinical evidence strategy and strengthening our reimbursement position, including CMS' proposal to keep Barostim in APC 1580 with appropriate payment for the implant procedure. The fundamentals of our business remain strong, and our maturing commercial organization positions us well for continued growth."
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> HF revenue in the U.S. totaled $12.1 million and $10.5 million for the three months ended June 30, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 387 and 339 for the three months ended June 30, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

108. On August 4, 2025, CVRx held a Q2 2025 Earnings Call ("Q2 2025 Call"). Defendants Hykes and Oasheim participated in the Q2 2025 Call.

109. During the Q2 2025 Call, Hykes reassured investors regarding its sales force,

stating, as follows:

> Let me remind you of our three strategic priorities for 2025. Our first priority is building a world-class sales organization that develops sustainable Barostim programs with deep therapy adoption. Our sales force transformation is progressing well and turnover is returning to more normal levels. The first wave of the sales reps hired earlier this year are getting up to speed and making meaningful contributions. We will continue hiring high quality talent, but at a more measured pace that aligns with our territory expansion plans rather than the accelerated hiring that was needed to support the transformation.
>
> With this foundation in place, we're now concentrating on onboarding the new reps and accelerating their path to productivity. Second, we're targeting centers with the highest potential for sustainable programs and implementing a best practice playbook to drive deep therapy adoption.

110. When asked by an analyst about reimbursement, Hykes stated:

> I think, today as a Category III therapy, we see 100% denials, as would anyone with the Category III code. We have also mentioned, though, we have done a very effective job in appealing those denials. And we believe we're doing better than average across the various payer segments in securing ultimately approval for our therapy. So, we're happy with where we are.
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> On January 1, the Category III code goes away and becomes a Category I code. And there's two important elements to that. The first is that the payers' ability to automatically deny coverage because of an experimental status, the Category III status, that goes away. And they're forced to use a human being to review each and every prior authorization, and deny it on the basis of medical necessity as evaluated by a human.
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> And so, that makes it much more, obviously, complex and expensive for them to do and requires that level of intervention. So, as you've seen with other therapies, perhaps we believe that while there will certainly still be prior authorizations required, the rate of approvals, the speed of the approvals, and the predictability of approval will improve, we think, significantly as of the first of the year.

111. On August 5, 2025, the Company issued its quarterly report on Form 10-Q for the second quarter 2025 with the SEC ("Q2 2025 Form 10-Q"). The Q2 2025 Form 10-Q was signed by Defendants Hykes and Oasheim.

112. The Q2 2025 Form 10-Q stated, in relevant part, as follows:

> The costs for the device and implantation procedure are reimbursed through various third-party payers, such as government agencies and commercial payers. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services while simultaneously developing processes to engage commercial payers. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be adjudicated on a claim-by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> HF revenue in the U.S. totaled $12.1 million and $10.5 million for the three months ended June 30, 2025 and 2024, respectively. HF revenue units in the U.S. totaled 387 and 339 for the three months ended June 30, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

113. On November 4, 2025, the Company issued a press release announcing financial results for the third quarter of 2025 ("Q3 2025 Press Release"). The Q3 2025 Press Release stated in relevant part as follows:

> "We're pleased with the solid progress we made in the third quarter as we continue to execute and build momentum across the organization," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our revised commercial strategy continues to show positive results. The development of our territories is progressing nicely as our newest reps are becoming increasingly more productive, resulting in both higher Barostim implant volumes and the expansion of our customer base. We're also pleased that CMS finalized our transition to Category I CPT codes, both improving patient access and removing key adoption barriers. Our focus remains on positively impacting the lives of patients who suffer from heart failure, and we are well positioned to drive deeper adoption going forward."
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> Revenue generated in the U.S. was $13.5 million for the three months ended September 30, 2025, an increase of $1.2 million, or 10%, over the three months ended September 30, 2024. Revenue units in the U.S. totaled 420 and 394 for the three months ended September 30, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

114. On November 5, 2025, CVRx held a Q3 2025 Earnings Call ("Q3 2025 Call"). Defendants Hykes and Oasheim participated in the Q3 2025 Call.

115. During the Q3 2025 Call, Hykes stated:

> Our newer reps are hitting their stride, driving procedure volumes and building productive relationships with the physicians and APPs that manage heart failure patients in the community.
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> Let me remind you of our three strategic priorities for 2025. Our first priority is building a world-class sales organization that develops sustainable Barostim programs with deep therapy adoption. Our sales force transformation is progressing well and turnover is returning to more normal

levels. The first wave of the sales reps hired earlier this year are getting up to speed and making meaningful contributions. We will continue hiring high quality talent, but at a more measured pace that aligns with our territory expansion plans rather than the accelerated hiring that was needed to support the transformation.

With this foundation in place, we're now concentrating on onboarding the new reps and accelerating their path to productivity. Second, we're targeting centers with the highest potential for sustainable programs and implementing a best practice playbook to drive deep therapy adoption.

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Looking ahead, we now have the fundamentals in place to positively impact the lives of a meaningful number of heart failure patients and to create significant value in doing so. Our sales team is becoming more productive and we're seeing positive signals from payers across the board. Our clinical evidence is expanding and our awareness efforts are gaining traction. Financially, we're demonstrating, improving operating leverage in our business model as we scale. Combined with our strong cash position, this gives us the resources and runway necessary to execute our strategy.

* * *

So, I would say, we're pleased with what we're seeing from the new reps, particularly those we've hired in the last three quarters. As Jared mentioned in his comments, I believe more reps today are active and contributing in the quarter than we've ever seen before. So, we're seeing them start to come up the curve and understand their roles and get comfortable in their territories and contribute. We're nowhere near yet seeing the full productivity that we would expect from these new hires. So, I think there's still some work to do there. And as we've communicated in the past, depending on the background of the individual and the territory that they're assuming or building from scratch, it can take 6 months to 9 months to 12 months for them to really start to contribute. But I would say at this point, we're really pleased with what we're seeing and no reason to think that we won't see continued improvement.

116. During the Q3 2025 Call, Hykes commented on patient access and reimbursement, stating:

On the coverage front, we are continuing to see encouraging trends and positive support from Medicare, Medicare Advantage and commercial

> payers. Taken as a whole, these reimbursement advancements are creating an increasingly solid foundation for patient access and facilitate our work to move Barostim towards standard of care. Our awareness efforts are focused on educating clinicians on the appropriate role of Barostim therapy in the treatment of heart failure.

117. On November 6, 2025, the Company issued its quarterly report on Form 10-Q for the third quarter 2025 with the SEC ("Q3 2025 Form 10-Q"). The Q3 2025 Form 10-Q was signed by Defendants Hykes and Oasheim.

118. The Q3 2025 Form 10-Q stated, in relevant part, as follows:

> The costs for the device and implantation procedure are reimbursed through various third-party payers, such as government agencies and commercial payers. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services while simultaneously developing processes to engage commercial payers. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be adjudicated on a claim-by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> Revenue generated in the U.S. was $13.5 million for the three months ended September 30, 2025, an increase of $1.2 million, or 10%, over the three

> months ended September 30, 2024. Revenue units in the U.S. totaled 420 and 394 for the three months ended September 30, 2025 and 2024, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

119. On December 3, 2025, CVRx attended the Piper Sandler Healthcare Conference ("Piper Sandler 2025 Conference"). Defendants Hykes and Oasheim participated in the Piper Sandler 2025 Conference.

120. During the Piper Sandler 2025 Conference, an analyst asked: "How do we think about the rep rebuild here? How is churn kind of trending, and then where are you going to get that group to by the end of this year?" Oasheim responded:

> As far as the churn or turnover that we had seen earlier in the year, it really did normalize back in Q3. So, we saw a little bit deeper turnover or transformation in the first and second quarter. That normalized. We were able to backfill a lot of those reps and see a return to normal turnover rates in the third and fourth quarter here.

121. On January 11, 2026, the Company issued a press release announcing preliminary financial results for the full year and fourth quarter of 2025 ("Preliminary FY 2025 Press Release"). The Preliminary FY 2025 Press Release stated, in relevant part, as follows:

> "We're pleased with our execution in 2025 as we delivered solid results while making significant strategic progress across the organization," said Kevin Hykes, President and Chief Executive Officer of CVRx. "Our focus on driving deeper penetration within high-potential accounts continued to gain traction, and we expanded our customer base as our sales organization developed throughout the year. The transition to Category I CPT codes, which took effect on January 1st, represents an important milestone that removes key adoption barriers and directly supports our commercial efforts going forward."

> "We enter 2026 well-positioned to accelerate growth with favorable reimbursement dynamics now in place, a maturing sales organization, and a strengthened balance sheet following our recent debt amendment. Our focus remains on positively impacting the lives of patients who suffer from heart failure, and we're confident in our ability to drive increased Barostim adoption in the year ahead."

122. On January 12, 2026, the Company filed a Form 8-K with the SEC disclosing that CVRx entered into an amendment (the "Amendment") to its existing Loan and Security Agreement dated October 31, 2022, as previously amended on March 13, 2023 (as amended, the "Loan Agreement"), with Innovatus Life Sciences Fund I, LP. The Loan Agreement was attached to the Form 8-K and provided Representations and Warranties and Affirmative Covenants which follow in pertinent part:

> **5.6 Regulatory Compliance.**... Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to have a Material Adverse Change.
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> * * *
>
> Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:
>
> **6.1 Government Compliance**.
>
> (a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change.

123. On January 12, 2026, the Company filed another Form 8-K with the SEC stating that it had entered into an Open Market Sale Agreement (the "Sale Agreement") with Jefferies LLC ("Jefferies"). Pursuant to the terms of the Sale Agreement, the

Company stated that it may offer and sell shares of the Company's common stock, $0.01 par value per share, having an aggregate offering amount of up to $50.0 million from time to time through Jefferies. Attached to the Form 8-K was the Sales Agreement, which included representations and warranties from CVRx, including the following:

> Regulatory Matters. (i) Neither the Company nor its subsidiaries has received any written notice of adverse filing, warning letter, untitled letter or other correspondence or notice from the FDA or other relevant regulatory authorities, or any other court or arbitrator or federal, state, local or foreign governmental or regulatory authority, alleging or asserting material noncompliance with the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the regulations promulgated thereunder, the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h), the Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), the exclusion law (42 U.S.C. § 1320a-7), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act), and any and all other similar state, local, federal or foreign law or regulations promulgated pursuant to such laws, including all laws and regulations applicable to ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import or export of the Company's products, each as amended from time to time (collectively, "Health Care Laws"); (ii) the Company and its subsidiaries are and have been in compliance with applicable Health Care Laws except where instances of non-compliance would not, singly or in the aggregate, reasonably be expected to have a Material Adverse Effect; (iii) neither the Company nor its subsidiaries received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any U.S. or non-U.S. federal, national, state, local or other governmental or regulatory authority, governmental or regulatory agency or body, court, arbitrator or self-regulatory organization (each, a "Governmental Authority") or third party alleging that any product operation or activity is in violation of any Health Care Laws and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement,

> investigation, arbitration or other action is threatened; (iv) the Company and its subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by applicable Health Care Laws, and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete, correct and not misleading on the date filed (or were corrected or supplemented by a subsequent submission), except where the failure to so file would not have a Material Adverse Effect; (v) neither the Company nor its subsidiaries or any of their respective directors, officers, employees or agents is or has been debarred, suspended or excluded, or has been convicted of any crime or engaged in any conduct that would result in a debarment, suspension or exclusion from any federal or state government health care program or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion; and (vi) the Company is not a party to and the Company does not have any ongoing reporting obligations pursuant to, any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by an Governmental Authority.

124. On January 14, 2026, CVRx attended the J.P. Morgan Healthcare Conference ("J.P. Morgan Conference"). Defendants Hykes and Oasheim participated in the J.P. Morgan Conference.

125. During the J.P. Morgan Conference, Hykes reassured investors about the sales force productivity, stating:

> So turning to our commercial approach, our go-to-market strategy is focused on driving Barostim to standard of care through three key pillars. The first is improving sales force productivity, the second is driving deep adoption in targeted centers, and the third is systemically addressing the barriers to adoption of this therapy that exists in the market.
>
> So, in the first case, our efforts to transform the sales force over the last year are now largely complete. Our turnover rates have returned to near normal, and we're focusing now on onboarding and improving the productivity of our new sales force. We're doing that through a number of ways. The first is optimizing the span of control in the field, so that our leaders in the field

> have the time and the bandwidth to mentor and train and improve the productivity of their new team members. The second is adding additional sales training personnel at the field level who can spend five days a week in the field riding with our teams and helping them understand the nature of the role and propagating best practices wherever possible.

126. On February 12, 2026, the Company issued a press release announcing financial results for the full year and fourth quarter of 2025 ("FY 2025 Press Release"). The FY 2025 Press Release stated, in relevant part, as follows:

> "We achieved key foundational goals in 2025, and we're heading into 2026 with increasing momentum. Our sales team is building experience and becoming more effective, and we're seeing strong support at high-potential centers. Additionally, the new Category I CPT codes, effective January 1st, remove automatic prior authorization denials. Finally, the initiation of the landmark BENEFIT-HF trial under CMS Category B IDE coverage is a major step that could allow us to triple our addressable market," said Kevin Hykes, President and Chief Executive Officer of CVRx. "We're confident that these developments will support our accelerated growth and make Barostim therapy more accessible for heart failure patients in the coming year."
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> Revenue generated in the U.S. was $14.9 million for the three months ended December 31, 2025, an increase of $0.6 million, or 4%, over the three months ended December 31, 2024. Revenue units in the U.S. totaled 478 and 460 for the three months ended December 31, 2025 and 2024, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

127. On February 12, 2026, CVRx held a FY 2025 Earnings Call ("FY 2025 Call"). Defendants Hykes and Oasheim participated in the FY 2025 Call.

128. During the FY 2025 Call, Hykes stated:

> Starting with our progress on the sales force, we undertook a deliberate transformation of our commercial organization to build the right team for our next phase of growth. We're pleased with the quality of talent that we've attracted and the progress that we're seeing in their development. By year-

end, we've expanded to 53 territories with 252 active implanting centers, up 10% and 13%, respectively. This expansion positions us with the capacity to drive meaningfully higher growth as our reps mature.

While integrating these many new representatives has created some near-term impact on growth, we're increasingly confident in the team's ability to execute our program-focused selling approach as they gain experience.

We've also implemented several important changes to accelerate the productivity of our sales team. We've optimized our field leadership structure, added dedicated training resources and focused our representatives on a narrower set of high-potential accounts, typically three to five, where they can drive deep adoption and truly change clinical behavior.

129. Concerning reimbursement, Hykes stated:

We're also seeing encouraging progress in our ongoing efforts to improve coverage. Our 30-day Medicare Advantage prior authorization approval rate reached 46% in 2025, up from 31% in 2024. This represented remarkable progress for therapy with the Category III code. And with the Category I code now in effect, we're optimistic that these approval rates will continue to improve.

130. Also, during the Q4 2025 Call, Oasheim stated:

So, I think as we look back to 2025, we did go through a bit of a reset after the first quarter, understanding that we had to cut a little bit deeper than initially anticipated within the sales organization. After that reset was done in the first quarter of 2025, we've seen pretty nice sequential growth from Q1 all the way through Q4 as we've continued to watch those new reps that we hired in 2024 and 2025 get further up the productivity curve.

131. On February 13, 2026, the Company issued its annual report on Form 10-K for the fiscal year ended December 31, 2025, and fourth quarter 2025 with the SEC ("FY 2025 Form 10-K"). The FY 2025 Form 10-K was signed by Defendants Yared and Oasheim.

132. The FY 2025 Form 10-K stated, in relevant part, as follows:

We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany and through distributors in Austria, Spain, and other

European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on HF specialists, interventional cardiologists, general cardiologists, advanced practice providers ("APPs"), electrophysiologists ("EPs"), vascular surgeons, and cardiothoracic surgeons. We are prioritizing our sales and marketing efforts on high volume cardiology centers that are strategically located and on educating and training physicians. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. We also highlight our compelling clinical benefits and value proposition to build awareness and adoption among physicians through targeted key opinion leader ("KOL") development, referral network education and direct-to-consumer marketing. We utilize direct communication channels to inform and educate patients about Barostim Therapy and utilize a qualification process to aid in the identification of the appropriate patients for our therapy. In the U.S., Barostim is reimbursed by the Centers for Medicare and Medicaid Services ("CMS") across all regions. We assist with reimbursement approvals, if required. We plan to continue actively expanding our direct sales force and commercial organization in the U.S., which is where we expect to focus most of our sales and marketing efforts in the near-term.

* * *

We primarily sell Barostim to hospitals through a direct sales organization in the U.S. and Germany, and through distributors in Austria, Spain, and other European countries. Our global sales and marketing team engages in sales efforts and promotional activities focused on HF specialists, interventional and general cardiologists, APPs, EPs, vascular surgeons, and cardiothoracic surgeons. We are continuing to actively expand our direct sales force and commercial organization in the U.S.

Our direct sales representatives, which we refer to as Territory Managers, generally have substantial and applicable medical device experience, specifically in the cardiovascular space, and market our products directly to the approximately 800 HF specialists, 20,000 general cardiologists and 2,500 EPs in the U.S. We support all aspects of the patient journey, which includes initial diagnosis, surgical support, and patient follow-up. Our Territory Managers are focused on prioritizing high volume cardiology centers that are strategically located and on educating and training physicians who have strong connectivity to the HFrEF patient population that may be eligible for our therapy. We also employ Field Clinical Specialists who generally have experience in medical device clinical support. Our Field Clinical Specialists work to ensure that every procedure is done correctly by educating the implanting physicians, including vascular surgeons and cardiothoracic

surgeons, about the technical aspects of Barostim and the implantation procedure.

Similar to our direct sales team, our marketing team has a significant amount of relevant expertise and a strong track record of success in the medical device industry. Our marketing organization is focused on building physician and APP awareness through targeted KOL development, referral network education and direct-to-consumer marketing.

In terms of patient education, we utilize direct communication channels to inform patients about Barostim Therapy and to enable them to connect with sites that offer Barostim. Our primary method of patient outreach is through digital marketing. We use a qualification process to aid in the identification of the appropriate patients for our therapy. The objective of this outreach is to inform potential patients about our education webinars and website, where they can find a wealth of information on HFrEF and the purpose, benefits, and risks of Barostim Therapy, based on our approved labeling.

In addition to driving broad awareness and increasing physician and patient education, our team has developed the in-house resources necessary to support physicians and patients in obtaining prior authorization approval for Barostim procedures.

* * *

We will continue to leverage our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist. We believe our market access team is highly effective in obtaining prior authorizations, including navigating the appeals process. In our discussions with commercial payers, we highlight our compelling and robust clinical data, including the long-term post-market BeAT-HF data, the potential economic cost-savings associated with our highly compliant treatment, increased patient demand and support from leading medical societies and KOLs. As our operations continue to grow, we intend to continue to further expand our market access team accordingly.

* * *

We have limited commercial sales experience marketing and selling Barostim, and if we are unable to continue to maintain and grow sales and marketing capabilities, we will be unable to generate sustained and increasing product revenue.

In order to generate future revenue growth, we plan to continue to expand the size and geographic scope of our U.S. direct sales and marketing organization. In order to increase our sales and marketing efforts, we will need to continue to retain, grow and develop a substantial number of direct sales personnel, which is a significant investment. There is significant competition for sales personnel experienced in relevant medical device sales. Once hired, the training process is lengthy because it requires significant education for new sales representatives to achieve the level of clinical competency with our products expected by physicians. Upon completion of the training, our sales representatives typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our product will often require or benefit from direct support from us. If we are unable to attract, motivate, develop, and retain a sufficient number of qualified sales personnel, and if our sales representatives do not achieve the productivity levels we expect them to reach, our revenue will not grow at the rate we expect, and our financial performance will suffer. Because the competition for direct medical sales personnel is high, we cannot be certain we will be able to hire and retain additional sales personnel on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified sales representatives would prevent us from expanding our business and generating anticipated revenue. Any of these risks may adversely affect our business.

* * *

If we fail to properly manage our growth effectively, our business could suffer.

We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, the hiring of our direct sales force requires significant management, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

* * *

If we fail to retain our key executives or recruit and hire new employees, our operations and financial results may be adversely affected while we attract other highly qualified personnel.

Transitions in executive leadership can adversely affect relationships with our customers, suppliers, and employees, make it difficult to attract and retain talent, and disrupt execution of our strategy, sales growth, and our efforts to enhance our operations. Additionally, such transitions can require significant payments to recruit and attract qualified employees to join our company and may involve severance payments to certain departing employees. Changes in key management positions may temporarily affect our financial performance and results of operations as the new management becomes familiar with our business and establishes their team dynamic.

* * *

If third-party payers do not provide adequate coverage and reimbursement for the use of Barostim, our revenue will be negatively impacted.

Medicare reimbursement levels are important to increasing adoption of Barostim and establishing Barostim as the standard of care because nearly two-thirds of the target patient population for Barostim is over the age of 65…. Any future decline in the amount Medicare is willing to reimburse our customers for procedures using Barostim could make it difficult for new customers to adopt Barostim and could create additional pricing pressure for us, which could adversely affect our ability to invest in and grow our business, or establish Barostim as the standard of care. Additionally, any declines in physician payments could make it difficult to promote the adoption of Barostim. From time to time, physicians and hospitals have in the past experienced, and others may experience, denials in Medicare and commercial reimbursement, which have delayed or may delay their willingness to schedule additional Barostim procedures.

* * *

The misuse or off-label use of our product may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in inappropriate promotion.

Barostim has been indicated for the improvement of symptoms of HFrEF by the FDA and the treatment of HFrEF and hypertension in the EEA. We may only promote or market Barostim for its specifically approved indications as described on the approved label. We train our marketing and sales force against promoting our products for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our product off-label when, in the physician's independent

professional medical judgment, he or she deems appropriate. There may be increased risk of injury to patients if physicians attempt to use our product off-label. Furthermore, the use of our product for indications other than those approved by the applicable regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

* * *

Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

* * *

Revenue generated in the U.S. was $51.9 million for the year ended December 31, 2025, an increase of $4.7 million, or 10%, over the year ended December 31, 2024. Revenue units in the U.S. totaled 1,648 and 1,522 for the years ended December 31, 2025 and 2024, respectively. The increase was primarily driven by continued growth as a result of the expansion into new sales territories and new accounts, as well as increased physician and patient awareness of Barostim.

133. Concerning compliance with laws and regulations, the FY 2025 Form 10-K stated, in relevant part, as follows:

We are subject to certain federal, state, and foreign fraud and abuse laws, transparency and privacy and security laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws and regulations could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims, and physician transparency laws. Our business practices and relationships with providers are subject to scrutiny under these laws. We are subject to privacy and security regulation related to patient, customer, employee, and other third-party information by both the federal government and the states and

foreign jurisdictions in which we conduct our business. In the U.S., the laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government;

These laws and regulations, among other things, constrain our business, marketing, and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians, or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

134. The statements in paragraphs 104 to 133 were false and misleading when made, and omitted to state material facts necessary to make the statements not misleading. Specifically, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) to induce sales growth, CVRx and/or its employees were engaged in illegal and unsustainable sales practices, including improperly marketing Barostim, offering or paying kickbacks, and providing false information to government health

insurance program which violated the FCA and the AKS; (b) CVRx's revenues were in part the product of such unlawful conduct and thus unsustainable; (c) the illegal sales and marketing activities increased the risk of a criminal and civil liability; and (d) that as a result of the foregoing, Defendants' public statements, including the Company's reported revenue, the purported growth drivers, compliance with the FCA and AKS, the effectiveness of its patient access and reimbursement strategy, and the effectiveness of CVRx's internal controls over financial reporting were materially false and misleading at all relevant times. Additionally, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) sales force turnover had not been stabilized and productivity remained materially below expectations because the sales organization required additional training, support, and restructuring; (b) a significant portion of the sales force were inexperienced, required extended training and ramp time, and were not yet capable of generating the productivity to meet revenue projections; and (c) that as a result of the foregoing, Defendants' public statements regarding the progress of the Company's sales force realignment and the transformation of its commercial organization were materially false and misleading at all relevant times.

135. On May 11, 2026, after the market close, the Company issued a press release announcing financial results for the first quarter of 2026 ("Q1 2026 Press Release"). The Q1 2026 Press Release stated, in relevant part, as follows:

> "We delivered a strong start to 2026, with U.S. revenue growing 22% as the investments we made in our team and programs throughout 2025 begin to translate into results," said Kevin Hykes, President and Chief Executive Officer of CVRx. "We are seeing continued progress from our sales organization and the successful activation of the first site and our first patient

enrolled in our BENEFIT-HF clinical trial. Together, these developments reinforce our confidence in the path ahead and in our ability to make Barostim more accessible to heart failure patients."

* * *

Revenue generated in the U.S. was $13.7 million for the three months ended March 31, 2026, an increase of $2.4 million, or 22%, over the three months ended March 31, 2025. Revenue units in the U.S. totaled 429 and 359 for the three months ended March 31, 2026 and 2025, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

136. Also, on May 11, 2026, after the market close, CVRx held a Q1 2026 Earnings Call ("Q1 2026 Call"). Defendants Hykes and Oasheim participated in the Q1 2026 Call.

137. During the Q1 2026 Call, Hykes stated:

Last year, we worked deliberately to strengthen our sales organization, refine our go-to-market approach, advance critical reimbursement initiatives and to secure approval for our landmark clinical trial. This quarter shows early evidence that the foundation we have built is translating into results.

As we move through 2026, we remain focused on executing against the same three strategic priorities that have guided our work to-date: building a world-class sales organization; driving deep adoption in targeted centers; and continuing to reduce the barriers to adoption of Barostim therapy.

Starting with our sales organization, we're pleased with the progress we're seeing from the team. We're seeing meaningful contributions from a broader and more experienced sales team, reflecting the quality of talent we've been able to attract, the discipline we brought to onboarding and training and the program-focused selling approach that the team is increasingly comfortable executing.

* * *

To wrap up, the first quarter reflects positive momentum across every part of our business. Our sales team is executing, the reimbursement environment is improving and our clinical evidence program is advancing on schedule.

> We remain focused on continuing to execute through the balance of 2026 and we're confident in the path ahead.
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> Our sales organization is maturing, the reimbursement environment is improving and the initiation of BENEFIT-HF opens a meaningful new chapter for our company and for the heart failure patients that we serve.

138. On May 12, 2026, before the market opened, the Company issued its quarterly report on Form 10-Q for the first quarter 2026 with the SEC ("Q1 2026 Form 10-Q"). The Q1 2026 Form 10-Q was signed by Defendants Hykes and Oasheim.

139. The Q1 2026 Form 10-Q stated, in relevant part, as follows:

> The costs for the device and implantation procedure are reimbursed through various third-party payers, such as government agencies and commercial payers. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services while simultaneously developing processes to engage commercial payers. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology ("CPT") codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be adjudicated on a claim-by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.
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> Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.
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> * * *

> Revenue generated in the U.S. was $13.7 million for the three months ended March 31, 2026, an increase of $2.4 million, or 22%, over the three months ended March 31, 2025. Revenue units in the U.S. totaled 429 and 359 for the three months ended March 31, 2026 and 2025, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

140. On this news, shares fell from a closing price of $6.86 per share on May 11, 2026, to $5.27 per share on May 12, 2026, a decline of $1.59 per share or 24%, on heavy volume.

141. In a May 11, 2026 report, a Canaccord Genuity analyst noted:

> Much of the call focused on management's comments about an increase in automatic prior-authorization denials in March, as payors began using AI to process claims to comply with new federal regulations aimed at reducing response times. CVRX is using both its in-house team and AI tools to continue adjudicating these denials…. [I]n January and February the Medicare Advantage prior-authorization approval rate for submissions managed by its in-house market access team (which handles more than 50% of total company MA volume, with MA representing roughly one-third of volumes) was 50%. However, beginning in late February, payors started using AI to automatically deny claims across the industry in order to comply with new federal regulations governing MA prior-authorization turnaround times. This brought CVRX's three-month approval rate to 46%. The company did not provide April data, but said it was encouraged by what it has seen so far and has begun applying its own AI tools to help counter these automatic denials.
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> Overall, the company said it is seeing meaningful contributions from a broader, more experienced sales team, reflecting both the quality of talent it has attracted and its continued focus on a program-based selling approach. Management also pointed to the addition of three territories in Q1 as evidence of its progress in filling territories and ramping them toward revenue generation.

142. The statements in paragraphs 135 to 139 were false and misleading when made, and omitted to state material facts necessary to make the statements not misleading.

Specifically, the Defendants made false and/or misleading statements or failed to disclose that: (a) to induce sales growth, CVRx and/or its employees were engaged in illegal and unsustainable sales practices, including improperly marketing Barostim, offering or paying kickbacks, and providing false information to government health insurance program which violated the FCA and the AKS; (b) CVRx's revenues were in part the product of such unlawful conduct and thus unsustainable; (c) the illegal sales and marketing activities increased the risk of a criminal and civil liability; and (d) that as a result of the foregoing, Defendants' public statements, including the Company's reported revenue, the purported growth drivers, compliance with the FCA and AKS, the effectiveness of its patient access and reimbursement strategy, and the effectiveness of CVRx's internal controls over financial reporting were materially false and misleading at all relevant times. Additionally, the Defendants made false and/or misleading statements and/or failed to disclose that: (a) sales force turnover had not been stabilized and productivity remained materially below expectations because the sales organization required additional training, support, and restructuring; (b) a significant portion of the sales force were inexperienced, required extended training and ramp time, and were not yet capable of generating the productivity to meet revenue projections; and (c) that as a result of the foregoing, Defendants' public statements regarding the progress of the Company's sales force realignment and the transformation of its commercial organization were materially false and misleading at all relevant times.

143. On June 9, 2026, before the market open, the Company issued a press release announcing that "Jared Oasheim, the Company's Chief Financial Officer, will be stepping

down from his role to pursue other professional opportunities." On this news, the price of CVRx stock declined $0.20 per share or 4% to close at $5.20 per share on June 9, 2026.

144. In a June 9, 2026 report, a Canaccord Genuity analyst commented that the CFO transition was "not anticipated" and that the Company did not include any "financial or guidance commentary in its press release."

145. On August 6, 2026, the Company issued a press release announcing financial results for the second quarter of 2026 ("Q2 2026 Press Release"). The Q2 2026 Press Release stated, in relevant part, as follows:

> "We are pleased with the strong revenue growth and margin performance in the second quarter along with the reimbursement progress we made, including the new Medicare Advantage coverage policy from Humana. However, we are not satisfied with our updated outlook for the balance of the year, driven by fewer sales territories than anticipated, lower sales force productivity and a prolonged challenge with one of our largest payers," said Kevin Hykes, President and Chief Executive Officer of CVRx. "We are taking direct action to address these headwinds, and our confidence in the long-term fundamentals of this business remains high, supported by strong growth observed in our most stable regions and encouraging early progress on the BENEFIT-HF trial and our broader clinical and reimbursement strategies."
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> Revenue generated in the U.S. was $14.8 million for the three months ended June 30, 2026, an increase of $2.5 million, or 21%, over the three months ended June 30, 2025. Revenue units in the U.S. totaled 466 and 391 for the three months ended June 30, 2026 and 2025, respectively. The increases were primarily driven by continued growth in the U.S. HF business as a result of the expansion into new sales territories, new accounts, and increased physician and patient awareness of Barostim.

146. On August 6, 2026, CVRx held a Q2 2026 Earnings Call ("Q2 2026 Call"). Defendants Hykes and Oasheim participated in the Q2 2026 Call.

147. During the Q2 2026 Call, Hykes revealed that sales force productivity problems were having a significant impact on revenue growth:

> Despite the positive quarter, we are seeing signs that the back half of the year will not be as strong as the first. As a result, we've lowered our revenue guidance for the year.
>
> My remarks today will cover three things: what is driving this change in outlook, what we're doing about it, and the longer term positive trends that we're seeing. We ended the quarter with 56 sales territories in the US, flat compared to the end of the first quarter. It is important to note that roughly 60% of quota-carrying territory managers have joined us in the last 18 months as we have worked to build the right organization for this next phase of growth.
>
> This rapid pace of hiring has strained our onboarding and training processes and the ability of our area sales directors to spend the time necessary to accelerate these new team members up the productivity curve. The scale of the turnover, the slower pace of the territory manager productivity ramp, and the concentration of these new hires in a subset of our regions are the primary factors behind today's guidance update.
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> Importantly, these challenges are not uniform across the business. In the regions where we have limited turnover and stable seasoned leadership executing our program development selling strategy, we're seeing strong double-digit growth, which indicates to us that when we have the right conditions in place, our strategy is indeed working.
>
> The sales force productivity challenges that we are facing are concentrated in specific regions that have a combination of new leadership and the highest turnover as a result of our sales force restructuring over the last 18 months. The combination of these two factors is distracting these regions from fully executing our market development plan, offsetting the success that we're seeing elsewhere in the country. Closing that gap is the focus of the steps that I will walk through next.
>
> First, we've continued to improve our hiring process and refine our hiring profiles to make sure that the people we bring on are the right fit from day one, limiting early turnover due to skills or expectations that are not aligned.
>
> Second, we are investing significantly in onboarding and training with new resources, roles, and materials designed to get reps productive more quickly. This includes a significant strengthening of our curriculum focused on

> practical account access skills, as well as extending the onboarding process beyond the initial three-month didactic phase to an additional three-month hands-on field mentorship. The objective of these changes is to accelerate time to productivity and to reduce sales director distraction by improving the readiness of our territory managers as they join their teams in the field.
>
> Third, we're creating multiple new field-based roles specifically focused on freeing up time for our area sales directors to more fully engage in coaching and developing the territory managers in their regions. This includes field-based reimbursement and business management personnel, as well as two vice president-level leaders to better support the area sales directors themselves. These additions are being funded through a reallocation of resources, not incremental spending. And as Jared will point out in his comments today, we are actually lowering our operating expense guidance for the year.
>
> And finally, we are redeploying senior leadership talent to roles that can have the fastest and most significant impact on our commercial execution. Our Chief Marketing Officer, Paul Verrastro, one of our most experienced and respected leaders, is moving into a new role providing direct support to our field teams to further accelerate the productivity of our new territory managers and area sales directors. Patrick Lyon, a key addition to our marketing team in Q4 of last year, is being promoted to lead our marketing organization, and we are confident in his ability to build upon Paul's outstanding contributions to date.

148. During the Q2 2026 Call, an analyst inquired about sales force turnover, to which Hykes responded:

> The overall scale of the turnover that we've experienced over the last 18 months as part of this transition, including continuing turnover in Q2 that is higher than we would have liked, has led to some of these challenges. And I can't characterize the percent that are more recent hires. The bulk of them are from the earlier years of the company. But this is the dynamic that's putting pressure on our onboarding and training processes, and that is leading to slower productivity ramps than we had anticipated seeing from this group, both in recently activated territories that aren't ramping up as quickly as they should or historically have, as well as our ability to move some of these new hires from the bench into new active territories.

149. Additionally, Hykes revealed reimbursement issues were impacting the Company and stated as follows:

> The second factor that impacts our view on the rest of the year is reimbursement. While there are a number of positive trends, we continue to be challenged by the change in behavior from our largest Medicare Advantage payer. For many quarters, this payer approved close to 80% of our prior authorizations within 30 days of submission, many within days upon receipt.
>
> In February, this payer implemented AI-based prior authorization tools, which resulted in an immediate increase in initial denials on the basis of administrative omissions. This was an attempt to comply with the shortened federal requirements for prior authorization review that went into place in January. This caused their 30-day approval rate to fall sharply in February and March to roughly 25%. Our own AI-based tools discussed on our last call helped bring that rate back up to approximately 40%. But this payer has since introduced further new tactics for denying claims, and the rate has now fallen back below 30%.
>
> As a result, providers who had grown used to approvals from that payer within a matter of days are now waiting far longer and seeing meaningfully lower initial approval rates. That shift has understandably made some physicians more hesitant to recommend Barostim therapy to their patients covered by that plan.

150. On August 6, 2026, the Company issued its quarterly report on Form 10-Q for the second quarter 2026 with the SEC ("Q2 2026 Form 10-Q"). The Q2 2026 Form 10-Q was signed by Defendants Hykes and Oasheim.

151. The Q2 2026 Form 10-Q stated, in relevant part, as follows:

> The costs for the device and implantation procedure are reimbursed through various third-party payers, such as government agencies and commercial payers. In the U.S., we estimate that 67% of our target patient population is Medicare-eligible based on the age demographic of the HFrEF patient population indicated for Barostim. As a result, we have prioritized coverage by the Centers for Medicare and Medicaid Services while simultaneously developing processes to engage commercial payers. All Medicare Administrative Contractors have retired their official automatic coverage denial policies for our Current Procedural Terminology ("CPT") codes, thereby allowing hospitals to submit payment requests for the Barostim procedure to be adjudicated on a claim-by-claim basis. Our reimbursement strategy involves continuing to broaden our current coverage and build our

in-house market access team to obtain appropriate prior authorization approvals in advance of treatment on a case-by-case basis where positive coverage policies currently do not exist.

* * *

Our U.S. sales have steadily increased since the pre-market approval of Barostim by the FDA in August 2019, and the subsequent reimbursement changes. We expect to continue to drive increases in revenue through our efforts to increase awareness of Barostim among physicians, patients and payers, and by the expansion of our U.S. sales force, as well as by seeking expanded labeling for Barostim. As a result, we expect that U.S. sales will continue to account for the majority of our revenue going forward.

* * *

We expect a lower rate of year-over-year revenue growth in the second half of fiscal 2026 than we experienced in the first half of fiscal 2026. This outlook is driven by fewer sales territories than anticipated, lower sales force productivity and a prolonged challenge with one of the largest payers. We are taking direct action to address these headwinds, including continuing to improve our hiring process, investing in onboarding and training and creating multiple field-based reimbursement and business management roles, funded through a reallocation of resources. We also continue to appeal prior authorization denials to advocate on behalf of patients. We continue to see strong growth in our most stable regions, while at the same time we continue to advance our BENEFIT-HF trial and our broader clinical and reimbursement strategies.

* * *

On May 14, 2026, we received a civil investigative demand ("CID") from the U.S. Department of Justice in connection with an investigation under the False Claims Act. The CID requested information and documents regarding an investigation into whether we caused the submission of false claims to government health insurance programs by improperly marketing our device, offering or paying kickbacks to healthcare providers or providing false information to government health insurance programs. We are cooperating with the investigation and are in the process of responding to the CID. We cannot predict the eventual scope, duration or outcome of this matter at this time and are unable to estimate the possibility of, or amount or range of, any possible financial loss related to this matter.

152. On this news, shares fell from a closing price of $5.94 per share on August 6, 2026, to $2.39 per share on August 7, 2026, a decline of $3.55 per share or 60%, on heavy volume.

153. In an August 6, 2026 report, a J.P. Morgan analyst commented:

> Management attributed the [sales guidance] revision to fewer sales territories than planned, lower sales force productivity, and a prolonged challenge with its largest Medicare Advantage payer. In response, CVRx is adding no new territories for the balance of the year and redeploying resources toward onboarding, training, and field support. Management framed the shortfall as an execution issue rather than one of demand, pointing to strong double-digit growth in its most stable regions as evidence the strategy works where turnover is low. Separately, CVRx disclosed a civil investigative demand from the DOJ related to certain sales and marketing practices, with the company fully cooperating.

154. In an August 6, 2026 report, a Piper Sandler analyst downgraded CVRx, noting as follows:

> [M]anagement highlighted sales force productivity issues in four of nine regions with the least-tenured leaders and highest turnover. These regions are experiencing negative implant growth and offsetting the double-digit growth observed in other regions. The company is implementing several initiatives to accelerate sales team productivity, but does not anticipate activating any new territories for the remainder of the year. Sales force disruption and subsequent productivity initiatives have remained a key topic for several quarters, and while we have previously given benefit of the doubt, we would like to see clear evidence of improving sales productivity before becoming more constructive.
>
> * * *
>
> CVRx continues to face pressure from its largest Medicare Advantage payer where prior authorization approval rates have been choppy this year. UNH's 30-day approval rate has fallen from 80% historically to 25% in February and March, briefly recovered to 40% through CVRx's eBase tools, and has since declined below 30%. We anticipate that physicians' hesitancy to recommend Barostim therapy due to these changing approval rates may take time to resolve.

155. In an August 7, 2026 report, a Canaccord Genuity analyst stated:

> Management cut FY26 revenue guidance to $58M-$60M … pointing to fewer sales territories than planned, slower salesforce productivity, and a prolonged prior-authorization challenge at its largest Medicare Advantage payer.
>
> * * *
>
> Roughly 60% of quota-carrying territory managers have joined within the past 18 months, which management said has overwhelmed its onboarding capacity. Simply put, CVRx tried to train too many people at once, and reps did not get the training they needed. The company believes these hires can be salvaged, but doing so will require additional sales infrastructure investment and several quarters of training before they become productive.

156. On August 11, 2026, the Company issued a press release announcing that "Robert John, Chief Revenue Officer, will depart the company, and that Paul Verrastro will assume the role of Interim Head of Sales, effective immediately."

157. On this news, shares fell from a closing price of $3.08 per share on Friday, August 14, 2026, to $2.75 per share on Monday, August 17, 2026, a decline of $0.33 per share or 11%, on heavy volume.

VI. ADDITIONAL SCIENTER ALLEGATIONS

158. CVRx and the Officer Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraud described herein could not have been perpetrated over a substantial period of time without the knowledge and complicity of the personnel at the highest level of the Company, including the Officer Defendants. These defendants were motivated to materially misrepresent the true nature of the Company's business, operations,

and financial affairs to the public and regulators in order to keep the Company's share price artificially high.

VII. LOSS CAUSATION

159. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This artificially inflated the price of CVRx shares and operated as a fraud or deceit on the Class. Later, when Defendants' prior misrepresentations and fraudulent conduct were disclosed to the market, the price of CVRx shares fell precipitously as the prior artificial inflation came out of the price over time. As a result of their purchases of CVRx shares during the Class Period, Plaintiff and other members of the class suffered economic loss, *i.e.*, damages, under the federal securities laws.

VIII. CLASS ACTION ALLEGATIONS

160. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons or entities that purchased or otherwise acquired shares of CVRx common stock during the Class Period. Excluded from the class are Defendants and their families, directors, and officers of the Company, as well as their families and affiliates.

161. The members of the class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members of the Class. Indeed, as of July

30, 2026, CVRx had over 26 million shares of common stock outstanding. Members of the Class may be identified from records maintained by CVRx or its transfer agent(s), and may be notified of the pendency of this action by mail using a form of notice customarily used in securities class actions.

162. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the class which predominate over questions which may affect individual class members include:

(a) Whether Defendants violated the Exchange Act;

(b) Whether Defendants engaged in a fraudulent scheme;

(c) Whether Defendants omitted and/or misrepresented material facts;

(d) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(e) Whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

(f) Whether reliance may be presumed pursuant to the fraud-on-the-market doctrine or presumption;

(g) Whether the price of CVRx common stock was artificially inflated;

(h) Whether Defendants' conduct caused the members of the class to sustain damages; and

(i) The extent of damage sustained by Class members and the appropriate measure of damages.

163. Plaintiff's claims are typical of those of the class because Plaintiff and the class sustained damages from Defendants' wrongful conduct.

164. Plaintiff will adequately protect the interests of the class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

165. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all class members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this case as a class action.

IX. INAPPLICABILITY OF STATUTORY SAFE HARBOR

166. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements plead in this Complaint. None of the specific statements alleged herein are forward looking. Many of the specific statements alleged herein were not identified as "forward-looking statements" when made.

167. To the extent that there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Moreover, to the extent that the statutory safe harbor does apply to any forward-looking statement, these statements were actionable because, at the time any forward-looking

statement was made, the particular speaker knew that the particular forward-looking statement was false or misleading or the forward looking statement was authorized or approved by an executive officer of the Company who knew that those statements were false or misleading when made.

X. PRESUMPTION OF RELIANCE

168. Plaintiffs are entitled to a presumption of reliance under the fraud-on-the-market doctrine. The market for the Company's securities was, at all times, an efficient market that promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the prices of the Company's securities. Throughout the Class Period:

(a) CVRx common stock was listed and actively traded on the NASDAQ;

(b) As a regulated issuer, CVRx filed periodic public reports with the SEC;

(c) CVRx regularly and publicly communicated with investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) CVRx was followed by several securities analysts employed by major brokerage firms who authored reports which were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

169. As a result of the foregoing, the market for CVRx shares promptly digested current information regarding CVRx from all publicly available sources and reflected such information in the price of the Company's common stock. Under these circumstances, all purchasers of CVRx common stock during the Class Period suffered similar injury through their purchase of CVRx common stock at artificially inflated prices, and the presumption of reliance applies.

170. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding CVRx's business operations—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of pricing visibility and effective sales practices for the Company's margins and profitability, that requirement is satisfied here.

COUNT I
For Violations of Section 10(b) of the Exchange Act and Rule 10b-5
Against CVRx and the Officer Defendants

171. Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

172. During the Class Period, CVRx and the Officer Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class

Period, did: (a) deceive the investing public, including Plaintiff and other class members, as alleged herein; and (b) cause Plaintiff and other members of the class to purchase CVRx shares at artificially inflated prices.

173. CVRx and the Officer Defendants: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's shares in an effort to maintain artificially high market prices for CVRx shares in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

174. CVRx and the Officer Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

175. During the Class Period, CVRx and the Officer Defendants made the false statements specified above, which they knew or recklessly disregarded to be false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

176. CVRx and the Officer Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. CVRx and the Officer Defendants engaged in

this misconduct to conceal CVRx's true condition from the investing public and to support the artificially inflated prices of the Company's shares.

177. Plaintiff and the class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for CVRx shares. Plaintiff and the class would not have purchased the Company's shares at the prices they paid, or at all, had they been aware that the market prices for CVRx shares had been artificially inflated by these Defendants' fraudulent course of conduct.

178. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other members of the class suffered damages in connection with their respective purchases of the Company's shares during the Class Period.

179. By virtue of the foregoing, CVRx and the Officer Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

COUNT II
For Violations of Section 20(a) of the Exchange Act
Against the Officer Defendants

180. Plaintiff repeats, incorporates, and realleges each and every allegation contained above as if fully set forth herein.

181. The Officer Defendants acted as controlling persons of CVRx within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, participation in and/or awareness of the Company's operations, direct involvement in the day-to-day operations of the Company, and/or intimate knowledge of the Company's actual performance, and their power to control public statements about CVRx, the Officer Defendants had the power and ability to control the actions of CVRx and its employees.

By reason of such conduct, the Officer Defendants are liable pursuant to Section 20(a) of the Exchange Act.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including attorneys' fees and expert fees; and

(d) Awarding such equitable/injunctive or other further relief as the Court may deem just and proper.

XII. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Lead Plaintiff hereby demands trial by jury of all issues that may be so tried.