

UNITED STATES OF AMERICA
Before the
SECURITIES AND EXCHANGE COMMISSION

SECURITIES ACT OF 1933
Release No. 9265 / October 6, 2011

SECURITIES EXCHANGE ACT OF 1934
Release No. 65501 / October 6, 2011

ADMINISTRATIVE PROCEEDING
File No. 3-14578

In the Matter of

HANSEN MEDICAL, INC.,

Respondent.

ORDER INSTITUTING CEASE-AND-DESIST PROCEEDINGS PURSUANT TO SECTION 8A OF THE SECURITIES ACT OF 1933 AND SECTION 21C OF THE SECURITIES EXCHANGE ACT OF 1934, MAKING FINDINGS, AND IMPOSING A CEASE-AND-DESIST ORDER

I.

The Securities and Exchange Commission (“Commission”) deems it appropriate that cease-and-desist proceedings be, and hereby are, instituted pursuant to Section 8A of the Securities Act of 1933 (“Securities Act”) and Section 21C of the Securities Exchange Act of 1934 (“Exchange Act”) against Hansen Medical, Inc. (“Hansen” or “Respondent”).

II.

In anticipation of the institution of these proceedings, Respondent has submitted an Offer of Settlement (the “Offer”) which the Commission has determined to accept. Solely for the purpose of these proceedings and any other proceedings brought by or on behalf of the Commission, or to which the Commission is a party, and without admitting or denying the findings herein, except as to the Commission’s jurisdiction over it and the subject matter of these proceedings, which are admitted, Respondent consents to the entry of this Order Instituting Cease-and-Desist Proceedings Pursuant to Section 8A of the Securities Act of 1933 and Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order (“Order”), as set forth below.

III.

On the basis of this Order and Respondent's Offer, the Commission finds¹ that:

Summary

1. This matter involves false financial reporting and related violations of the federal securities laws by Hansen Medical, Inc., a medical equipment company based in Mountain View, California. On four separate occasions in 2008 and 2009, Hansen's top sales executives were involved in fraudulent sales transactions, causing the company to report quarterly revenue to investors that had been improperly and materially overstated.

2. Under Generally Accepted Accounting Principles ("GAAP") and the company's own policies, Hansen could recognize revenue only when a sale was complete – which, for most transactions, meant that the company's complex medical equipment had been installed in the hospital and training had been provided to at least one physician who would be operating it. Facing intense pressure to make sales and facilitate Hansen's ability to raise capital from investors, these sales executives engaged in myriad tricks to make it falsely appear that sales had been completed. For example, on multiple occasions, Hansen personnel "installed" the equipment at the customer site before the customer was ready for it, and then, unbeknownst to company finance personnel and auditors, immediately dismantled the equipment and put it in storage until months later. In another instance, when the required training could not be provided to a customer's physicians by quarter end, Hansen personnel forged a doctor's signature and provided the falsified training form to the company's finance personnel to allow revenue recognition.

3. In August 2009, one of the fraudulent transactions was brought to light by an anonymous whistleblower. On November 19, 2009, following an internal investigation, Hansen announced the filing of restated financial results for the years ended December 31, 2007 and 2008, and the first two quarters of fiscal year 2009.

Respondent

4. **Hansen Medical, Inc.** is a medical equipment company incorporated in Delaware and headquartered in Mountain View, California. Hansen's common stock is registered with the Commission pursuant to Section 12(b) of the Exchange Act and is listed on the NASDAQ Global Market under the ticker symbol HNSN.

¹ The findings herein are made pursuant to Respondent's Offer of Settlement and are not binding on any other person or entity in this or any other proceeding.

Facts

A. Background

5. Hansen was founded in 2002, and had its Initial Public Offering of stock in 2006. In May 2007, Hansen received Food and Drug Administration approval for its product, a complex piece of medical equipment, known as the Sensei Robotic Catheter System (“Sensei system”), sold primarily to hospitals for use in cardiac surgical procedures. Hansen recognized revenue on its first domestic Sensei system in June 2007.

6. From 2007 through at least November 2009, Hansen based its revenue recognition policy on American Institute of Certified Public Accountants, Statement of Position 97-2, *Software Revenue Recognition* (hereafter “SOP 97-2”), because Hansen determined that software was more than incidental to the functioning of its Sensei system. Under Hansen’s policy, in order to recognize revenue on certain types of transactions, the Sensei system had to be delivered to the customer, installed (usually at the customer site), and at least one physician had to be trained to use the Sensei system. As the installation and training services were not deemed to be perfunctory, Hansen’s revenue recognition policy for these transactions was to defer the entire amount of the revenue on its Sensei sales until Hansen had completed both physician training and installation for its customers.

7. Most of Hansen’s sales contracts for Sensei systems required Hansen to install the systems at the customer site, which could take up to two days’ time due to the complexity of the equipment and the battery of tests that Hansen would run to ensure the systems were in good working order. In addition, most of Hansen’s sales contracts required the company to provide training to at least one physician who intended to use the Sensei system, which included having the physician travel to Hansen facilities in either Mountain View, California or Cleveland, Ohio.

8. As evidence that installation had been completed, Hansen’s field services group, which was responsible for installing Sensei systems at a customer site, would submit to Hansen’s finance department an installation completion form that was signed by the Hansen installer and a representative from Hansen’s customer. As evidence that physician training had been completed, Hansen’s clinical group, which was responsible for conducting physician training, would submit to Hansen’s finance department a training acknowledgment form signed by the Hansen trainer and the physician. These completed forms were included in the revenue recognition files that were reviewed by Hansen’s finance group and the company’s outside auditors to allow them to determine whether and when Hansen could recognize revenue on particular sales transactions.

9. In June 2008, Hansen created a new officer-level position and hired a new Senior Vice President of Commercial Operations who was responsible for overseeing Hansen’s sales organization as well as Hansen’s field services group and clinical group.

B. Hansen Reported Materially Inflated Revenue In Its Financial Statements for the Third Quarter of 2008 Due To Incomplete Delivery of Its Product

10. In September 2008, Hansen was engaged in negotiations with a customer hospital (hereinafter “Hospital A”) to sell the hospital a Sensei system. On September 15, 2008, Hospital A agreed to pay Hansen \$700,000 to acquire a Sensei system. Per Hansen’s revenue recognition policy, Hansen had to complete several requirements, including installation of the Sensei system at Hospital A, before Hansen could recognize revenue on the sale.

11. The terms of the contract between Hospital A and Hansen required that delivery and installation be completed by the end of September 2008. On September 18, 2008, Hospital A informed Hansen that it needed time to prepare its lab for the equipment, that it was overwhelmed with installations and that it had to prioritize its delivery schedules. Therefore, Hospital A requested that Hansen delay installation of the Sensei system by four months, which was well past the end of Hansen’s third quarter 2008. Hansen sales executives, however, including Hansen’s Senior Vice President of Commercial Operations and Hansen’s Vice President of Sales, wanted to have the system installed by September 30, 2008 so that Hansen could recognize revenue on the sale in that quarter.

12. On or about September 19, 2008, Hansen sales executives, including the Senior Vice President of Commercial Operations and Hansen’s Vice President of Sales, participated in a conference call with Hospital A management. During the call, the Hansen sales executives pressured Hospital A to accept delivery of the system by September 30, 2008 even though the hospital’s lab was under construction. To overcome the hospital’s objections about taking the Sensei system before the lab was ready, Hansen sales executives agreed that Hansen’s field services group would install the Sensei system before September 30, 2008, immediately de-install the system, place it into storage at the hospital, and come back months later when the lab was ready to re-install the system. Hansen personnel further agreed to absorb all of the costs associated with the re-installation of the Sensei system.

13. On September 26, 2008, Hansen personnel “installed” the Sensei system at Hospital A, but then immediately de-installed the system and placed it into storage at the hospital. Hansen recognized approximately \$700,000 in revenue for the sale in the third quarter ended September 30, 2008. Under GAAP, it was inappropriate for Hansen to recognize revenue on the transaction in the third quarter of 2008 because Hansen’s delivery of the product was temporary and was nothing more than form over substance. As of September 30, 2008, Hansen still had outstanding obligations to the hospital to re-install the equipment at a later date at Hansen’s cost.

14. On November 5, 2008, Hansen filed with the Commission its Form 10-Q for the quarter ended September 30, 2008. The financial statements included in Hansen’s Form 10-Q improperly reported \$700,000 in revenue from the sale to Hospital A. As a result, Hansen reported materially inflated product revenue in its financial statements.

15. Neither Hansen’s finance personnel, who were responsible for making determinations about revenue recognition on the sale, nor Hansen’s outside auditors knew that Hansen had further obligations to re-install the equipment at Hansen’s cost on a future date. In the

spring of 2009, months after Hansen recognized revenue on the sale, Hansen personnel completed Hansen's delivery obligations by re-installing the Sensei system at Hansen's expense at Hospital A.

C. Hansen Reported Materially Inflated Revenue In Its Financial Statements for the Fourth Quarter of 2008 Due to Two Improper Sales Transactions Totaling More Than \$1.3 Million

i. Hansen's Financing Efforts

16. In December 2008 and through Hansen's first quarter of 2009 ending March 31, 2009, Hansen was seeking investment funds to provide operating capital for the company. During this period, Hansen had an effective registration statement, filed with the Commission in March 2008, in which it was offering to sell up to \$75,000,000 of newly-issued Hansen common stock. Hansen management, including Hansen's senior sales executives, believed that Hansen needed to show strong Sensei system sales to attract potential investors.

17. On December 19, 2008, less than two weeks before Hansen's 2008 fiscal year end, Hansen's Senior Vice President of Commercial Operations sent an email to the Hansen sales organization. In the message, he chastised his subordinates for creating a situation that is "not acceptable from a senior sales team." He noted that "this is a very important quarter with additional funding on the line for Hansen" and, therefore, "it is imperative that we find a way to finish in an acceptable manner." He then tallied up the potential transactions in the sales pipeline and threatened the team that "finish[ing] below 12 systems [sales]" would jeopardize the company's current funding efforts or require layoffs. He signed the email "Grumpy Santa." Two improper sales transactions described below followed shortly thereafter.

ii. Hansen Personnel Falsify Key Documents Required for Revenue Recognition in a December 2008 Sales Transaction

18. In the spring of 2008, a customer hospital (hereinafter "Hospital B") agreed to purchase a Sensei system for \$660,000, but had to wait for certain approvals from the State of Connecticut before it could complete the purchase. Hansen's Senior Vice President of Commercial Operations was anxious to have the transaction with Hospital B close before the end of 2008 so that Hansen could report revenue from the sale. Thus, on December 24, 2008, one week before Hansen's fiscal year end, he threatened Hospital B with a price increase if the transaction did not close in 2008. On December 27, 2008, Hospital B informed Hansen's Senior Vice President of Commercial Operations that the State of Connecticut had supplied the necessary approvals to allow Hospital B to purchase the Sensei system.

19. As part of the sales contract with Hospital B, and in order to recognize revenue on the sale, Hansen was obligated to provide training on the Sensei system to at least one Hospital B physician who planned to use the equipment. Hansen was also obligated to install the system at Hospital B. Both training and installation were necessary to fulfill the "delivery" requirement under Hansen's revenue recognition policy. As of December 28, 2008, no Hospital B doctors had been trained on the Hansen equipment, and the lab in which Hospital B intended to use the Sensei system was not ready to accommodate the installation of the Sensei system. Hansen's senior sales

executives, including the Senior Vice President of Commercial Operations and the Vice President of Sales, were aware of the training and installation issues.

20. With only three business days left in Hansen's fourth quarter 2008, Hansen personnel were unable to schedule a training session for the Hospital B doctors that would occur before the end of December 2008, thereby allowing the company to recognize revenue on the transaction that quarter. To recognize revenue in the fourth quarter of 2008, despite the lack of required training, Hansen's Senior Vice President of Commercial Operations and Hansen's Vice President of Sales, devised a plan to falsify the training paperwork.

21. To that end, on December 30, 2008, one day before the end of Hansen's 2008 fiscal year, a Hansen clinical training employee emailed the Hospital B doctors requesting their signatures on required physician training forms, acknowledging they had been trained even though they had not. The Hansen employee promised that Hansen would provide the physicians with training sometime in 2009. Although the clinical training employee was concerned about possible patient safety issues with falsely certifying that a doctor had been trained on the Sensei system, senior Hansen sales executives directed the employee to make the request.

22. When the Hospital B doctors did not respond to the Hansen employee's email on December 30, Hansen personnel forged the signature of one of the Hospital B doctors on the training acknowledgement form. The form was then provided to Hansen personnel responsible for assembling Hansen's revenue recognition files. Thereafter, Hansen recognized \$660,000 on the sale to Hospital B in its financial statements for the fourth quarter of 2008. At the time revenue was recognized, neither Hansen's finance department nor its outside auditors knew that the physician training form had been falsified. Under GAAP, and Hansen's revenue recognition policy, Hansen should not have recognized revenue on the sale as of December 31, 2008 because Hansen had not completed physician training.

23. In addition to the issues with the physician training form for Hospital B, Hansen also failed to complete installation of the Sensei system before the end of the fourth quarter 2008. Specifically, Hansen service personnel temporarily "installed" the Sensei system at Hospital B on December 31, 2008, the last day of Hansen's fiscal year, but within minutes of the installation, Hansen personnel began de-installing the system. It was then placed into storage because the lab in which Hospital B intended to use the Sensei system was not prepared for the installation of the equipment. Hansen sales executives had committed to re-install the Sensei system at a later date in 2009 at Hansen's expense when the lab in which Hospital B intended to use the system was ready. Under GAAP, it was inappropriate for Hansen to recognize revenue on the transaction in the fourth quarter of 2008 because Hansen's delivery of the product was temporary, like the third quarter 2008 Hospital A deal, and was nothing more than form over substance. As of December 31, 2008, Hansen still had outstanding obligations to the hospital to completely re-install the equipment at Hansen's cost. Neither Hansen's finance personnel, who were responsible for making determinations about revenue recognition on the sale, nor Hansen's outside auditors knew that Hansen had further obligations to re-install the equipment at Hansen's cost. Hansen ultimately re-installed the Sensei system in July 2009.

iii. A Hansen Executive Enters Into an Undisclosed Oral Side Agreement in a December 2008 Sales Transaction

24. In a second December 2008 transaction, a customer hospital (hereinafter “Hospital C”) sought to purchase a Sensei system, but did not have sufficient funds. To complete the transaction by the end of 2008, Hansen’s Senior Vice President of Commercial Operations negotiated with a third party leasing company to buy the system from Hansen and lease it to Hospital C. On December 22, 2008, the leasing company purchased a Sensei system from Hansen for \$650,000, and then entered into a leasing arrangement with Hospital C.

25. Under the terms of the lease, Hospital C was required to pay \$20,000 per month in leasing fees, but had the right to return the system to the leasing company in six months with the payment of a minimal \$90,000 restocking fee. Under the leasing company’s contract with Hansen, the leasing company did not have the right to return the Sensei system to Hansen if the hospital elected not to continue the lease. As a result of these terms, the leasing company expressed concern to Hansen’s Senior Vice President of Commercial Operations about the financial risk the leasing company was undertaking if Hospital C returned the Sensei system.

26. To minimize the leasing company’s risk, Hansen’s Senior Vice President of Commercial Operations orally agreed that Hansen would take care of the leasing company if the hospital returned the system. Hansen’s Senior Vice President of Commercial Operations did not inform Hansen’s finance department about his oral agreement with the leasing company. In fact, the Senior Vice President of Commercial Operations falsely confirmed in a March 2009 letter to Hansen’s outside audit firm that he had disclosed all oral agreements with respect to sales that occurred in December 2008.

27. Thereafter, Hansen recognized approximately \$650,000 in revenue on the sale to the leasing company in its financial statements for Hansen’s fourth quarter ended December 31, 2008.

28. Under GAAP, it was improper for Hansen to recognize revenue on the sale because Hansen had not transferred all of the risks and rewards of ownership of its Sensei system to the leasing company. To the contrary, the oral side agreement that Hansen would take care of the leasing company if the hospital returned the equipment created future obligations for Hansen, including the possibility that it would have to accept a return of the product or help find another buyer.

29. Ultimately, Hospital C returned the Sensei system to the leasing company in the fall of 2009. At this time, the leasing company principal informed a Hansen executive of his oral side agreement with the Senior Vice President of Commercial Operations. Hansen agreed to take the Sensei system back and refunded the leasing company \$500,000 of its purchase price.

D. Hansen Reports Inflated Revenues In Its 2008 Form 10-K As A Result of the Fraudulent Hospital A, Hospital B and Hospital C Transactions

30. On March 16, 2009, Hansen filed with the Commission its Form 10-K for the fiscal year ended December 31, 2008. The financial statements filed with Hansen’s Form 10-K included

\$1,310,000 in improperly reported revenue for the fourth quarter of 2008 from the sales to Hospital B and Hospital C. In addition, Hansen's Form 10-K for the fiscal year 2008 included inflated annual revenues as a result of the improperly reported revenues from the Hospital A, Hospital B, and Hospital C transactions.

31. In April 2009, Hansen filed a supplemental prospectus with the Commission as part of the company's offer to sell Hansen common stock to the public. The prospectus incorporated by reference Hansen's Form 10-K for the fiscal year ended December 31, 2008. On April 22, 2009, Hansen sold more than 11.5 million shares of its common stock to investors, resulting in approximately \$35 million in net proceeds to the company.

E. Hansen Reported Materially Inflated Revenue In Its Financial Statements for the First Quarter of 2009 Due To Incomplete Delivery of Its Product

32. On March 12, 2009, as the end of Hansen's first quarter of 2009 drew near, Hansen's Senior Vice President of Commercial Operations sent Hansen's sales force an email that he signed "Mr. Nervous." In the email, the Senior Vice President noted the importance of the Q1 '09 results to the company's funding prospects and made clear that he expected to complete at least 10 Sensei system sales by the end of the first quarter.

33. One of those anticipated sales was to a customer hospital (hereinafter "Hospital D"). In the final days of the quarter, another Hansen sales executive requested that Hospital D sign the contract and accept installation of the system, stating in an email, "I can't stress enough how important this sale is to our organization. We are in the middle of a \$50 million funding round. Therefore, everyone in the organization was counting on this sale." This sales executive also emailed another Hospital D executive on March 27, 2009, offering to discount the system price if it would help close the deal, and stating "this sale is critical to our organization as we are in the middle of a \$50 million funding round. It is more important for me to hit a unit number than it is to achieve a specific sales price."

34. Hansen's sales executives, including Hansen's Senior Vice President of Commercial Operations and Hansen's Vice President of Sales, rushed to complete the Hospital D transaction on March 31, 2009, the last day of Hansen's first quarter. Hansen personnel and Hospital D were still negotiating key terms of the contract until late in the evening of March 31. On March 31, 2009, Hospital D agreed to pay \$550,000 for a Sensei system.

35. Hospital D had not completed renovations to the lab where it intended to install the Sensei system as of March 31, 2009. Therefore, on March 31, Hansen "installed" the system in the lab, but, at the hospital's request, Hansen personnel immediately de-installed the system and placed it in storage at the hospital.

36. Hansen recognized approximately \$550,000 in revenue for the Hospital D sale in the first quarter ended March 31, 2009. Under GAAP, it was inappropriate for Hansen to recognize revenue on the transaction in the first quarter of 2009 because Hansen's delivery of the product was temporary and was nothing more than form over substance. As of March 31, 2009, Hansen still had outstanding obligations to re-install the equipment at a later date at Hansen's cost.

37. On May 8, 2009, Hansen filed with the Commission its Form 10-Q for the quarter ended March 31, 2009. The financial statements filed with Hansen's Form 10-Q included \$550,000 in improperly reported revenue from the sale to Hospital D. As a result, Hansen reported materially inflated product revenue in its financial statements.

38. Neither Hansen's finance personnel, who were responsible for making determinations about revenue recognition on the sale, nor Hansen's outside auditors knew that Hansen had further obligations to re-install the equipment at Hansen's cost. In the second quarter of 2009, Hansen recognized revenue on the sale after Hansen personnel completed Hansen's delivery obligations by re-installing the Sensei system at Hospital D at Hansen's expense.

F. Hansen's Restatement And Subsequent Events

39. In August 2009, Hansen received an anonymous whistleblower complaint, reporting the falsified physician training form in the sales transaction with Hospital B. In response to the complaint, Hansen's audit committee engaged outside legal counsel to conduct an internal investigation. The internal investigation examined not only the forgery in the Hospital B sale, but was also expanded to include a review of sales transactions completed by Hansen from June 2007 (when Hansen recognized revenue from its first domestic product sale) to June 2009. In October 2009, as a result of information gathered in the internal investigation, Hansen requested the resignation of its Senior Vice President of Commercial Operations and terminated the employment of its Vice President of Sales.

40. Following the internal investigation, Hansen announced in Forms 8-K, filed on October 19, 2009 and November 10, 2009, that it intended to issue restated financial statements for the fiscal years ended December 31, 2007 and 2008, for each of the quarters in 2008, and for the first two quarters in 2009. On November 16, 2009, Hansen filed restated financial statements for those periods after determining that revenue from multiple sales transactions had been improperly reported. Included within the restated transactions were the four specific fraudulent transactions discussed in detail above.

Hansen's Remedial Efforts

41. After Hansen's violations came to light in August 2009, Hansen promptly undertook significant remedial efforts. These efforts included undertaking an internal investigation, requesting the resignation of Hansen's Senior Vice President of Commercial Operations and terminating the employment of its Vice President of Sales for their respective roles in the problematic sales transactions, and taking other personnel action as a result of the misconduct. Hansen also reorganized the management structure of the company so that the sales, clinical and field service teams no longer reported to the same supervising officer, which was intended to ensure that each team has the proper oversight. In addition, Hansen issued oral and written reprimands to eight Hansen employees for their respective failures of judgment that contributed to Hansen's misstatement of revenue. Hansen has also provided increased and improved training to all Hansen employees regarding their ethical obligations and the company's revenue recognition policies, and implemented additional corporate governance and internal control policies, including controls relating to revenue recognition. Hansen has also implemented

a revised compensation structure for Hansen's sales group that is intended to separate commission payments from achieving revenue recognition on sales transactions.

42. In determining to accept the Offer, the Commission considered the significant remedial acts Hansen promptly undertook, Hansen's voluntary disclosure of these matters to the Commission, and cooperation afforded to the Commission staff.

Violations

Hansen Medical, Inc. Violated Sections 17(a)(2) and 17(a)(3) of the Securities Act

43. As a result of the conduct described above, Hansen violated Sections 17(a)(2) and 17(a)(3) of the Securities Act. In the offer or sale of securities, Section 17(a)(2) makes it unlawful "to obtain money or property by means of any untrue statement of a material fact or any omission to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;" and Section 17(a)(3) proscribes "any transaction, practice, or course of business which operates or would operate as a fraud or deceit on the purchaser." Violations of Sections 17(a)(2) and 17(a)(3) may be established by a showing of negligence. Aaron v. SEC, 446 U.S. 680, 697 (1980); SEC v. Glt. Dain Rauscher, Inc., 254 F.3d 852, 856 (9th Cir. 2001).

Hansen Medical, Inc. Violated Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act and Rules 12b-20, 13a-1, and 13a-13 thereunder

44. As a result of the conduct described above, Hansen violated Sections 13(a), 13(b)(2)(A), and 13(b)(2)(B) of the Exchange Act, and Rules 12b-20, 13a-1, and 13a-13 thereunder by filing inaccurate periodic reports with the Commission, by failing to make and keep accurate books and records, and by failing to devise and maintain an adequate system of accounting controls.

IV.

In view of the foregoing, the Commission deems it appropriate to impose the sanctions agreed to in Respondent Hansen's Offer.

Accordingly, it is hereby ORDERED that:

Pursuant to Section 8A of the Securities Act and Section 21C of the Exchange Act, Hansen Medical, Inc. cease and desist from committing or causing any violations and any future violations of Sections 17(a)(2) and 17(a)(3) of the Securities Act, and Sections 13(a), 13(b)(2)(A) and 13(b)(2)(B) of the Exchange Act and Rules 12b-20, 13a-1, and 13a-13 thereunder.

By the Commission.

Elizabeth M. Murphy
Secretary