IN THE COURT OF CHANCERY OF THE STATE OF DELAWARE

CHANNEL MEDSYSTEMS, INC., a Delaware corporation, Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, a Delaware corporation, and NXT MERGER CORP., a Delaware corporation, Defendants.	C.A. No. _____ **PUBLIC VERSION EFILED SEPTEMBER 17, 2018**

VERIFIED COMPLAINT

Plaintiff Channel Medsystems, Inc. ("Channel"), by and through its undersigned counsel, hereby files this Verified Complaint against Defendants Boston Scientific Corporation and NXT Merger Corp. (together, "Defendants" or "BSC") and alleges, upon knowledge with respect to its own acts and upon information and belief as to all other matters, as follows:

NATURE OF DISPUTE

1. This is a breach of contract action brought by Channel, a start-up medical device company, seeking to prevent Defendants from backing out of their obligations under the November 1, 2017 Merger Agreement and Plan of Merger by and between Channel and BSC (the "Merger Agreement"), pursuant to

which BSC will acquire the remaining 80% of outstanding shares in Channel—if certain regulatory conditions are met—for up to $275 million (the "Transaction").[1]

2. Channel is currently seeking approval from the U.S. Food and Drug Administration (the "FDA") for its flagship product, the Cerene Cryotherapy Device (the "Cerene Device"), which is a breakthrough medical device used to treat heavy menstrual bleeding. The commercial prospects for the Cerene Device following likely FDA approval make Channel an attractive partner for BSC. Nevertheless, BSC did not want to bear the risk that the Cerene Device would not be approved by the FDA, so it negotiated specific terms in the Merger Agreement such that BSC could only be required to close on the Transaction in the event that the Cerene Device receives FDA approval by September 30, 2019.

3. Rather than waiting to see if Channel actually secures such regulatory approvals from the FDA next year, as it is contractually obligated to do, BSC—which, for reasons known only to itself, no longer wishes to proceed with the Transaction—has decided to take matters into its own hands to try to escape the deal. Thus, on May 11, 2018, Defendants delivered to Channel a letter purporting to terminate the Merger Agreement on manufactured grounds that Channel had allegedly (i) fraudulently induced BSC to enter into the Merger Agreement, and

---

[1] A true and correct copy of the Merger Agreement is attached as Exhibit A.

(ii) breached its representations and warranties under the Merger Agreement, and that such breaches gave rise to a material adverse effect ("MAE"). As set forth below, Channel neither committed fraud on BSC nor breached its representations and warranties. And, there certainly has not been an MAE. On the contrary, the only thing that has changed about Channel since the time of signing the Merger Agreement is BSC's desire to consummate a transaction on which it has now apparently soured.

4. The basis for BSC's claim for termination is an incident involving one of Channel's former employees. Roughly two months after the parties entered into the Merger Agreement, Channel discovered that its then-Vice President of Quality Assurance had falsified certain expense reports as part of a fraudulent scheme by which he ultimately stole about $2.57 million from Channel. That employee was quickly fired, and the matter was turned over to the proper criminal authorities.

5. In the course of investigating the ex-employee's misconduct, Channel discovered that the ex-employee had fabricated certain reports in order to make the detection of his fraud less likely. Unbeknownst to the company at the time, some of these falsified reports were contained in Channel's submissions to the FDA seeking approval of the Cerene Device.

6. Importantly, these falsified reports are highly unlikely to impact the FDA's decision to approve the Cerene Device. For example, nothing done by

the ex-employee involved had any impact whatsoever on the clinical study which Channel believes demonstrates that the Cerene Device is both safe and effective. Thus, the misconduct at issue poses no threat to the Cerene Device's safety and/or efficacy, nor to the ability of Channel to secure approval for the Cerene Device. In fact, approval for the Cerene Device by the FDA remains on track.

7. Having discovered this misconduct, and that certain falsified reports were submitted to the FDA, Channel was fully transparent with the FDA, alerting them on January 25, 2018 of the ex-employee's misconduct. Channel has had ongoing discussions with the FDA, including a March 16, 2018 meeting in which Channel gave a presentation on everything it had learned and what it had done or planned to do in order to remedy the issues it had identified. Channel also kept BSC promptly and fully apprised of all these developments and discussions.

8. In short, Channel has informed the FDA of the key aspects of the ex-employee's fraud, the investigation conducted by Channel (and its independent consultants), and its remediation efforts. [redacted]. Since then, Channel has worked quickly to repeat (or perform for the first time) the modest number of tests which were reported in the falsified

documentation initially submitted to the FDA and has re-submitted its full approval package for the Cerene Device to the FDA, and the FDA has accepted that submission for review.

9. There is every reason to believe that the FDA will approve the Cerene Device well in advance of the deadline under the Merger Agreement. Once FDA approval is obtained, which is likely to occur in the first quarter of 2019, the key closing condition under the Merger Agreement will have been satisfied.

10. Even if, contrary to every indication provided to date, the issues arising from the ex-employee's misconduct were somehow to prevent or significantly delay FDA approval, BSC has already protected itself against such a contingency through the terms of the Merger Agreement. If September 30, 2019 comes, and the Cerene Device has not received FDA approval, BSC is free to walk away.

11. That outcome, however, appears unlikely. As evidenced by the fact that the FDA has given Channel absolutely no indication that there will be any issues with approval of the Cerene Device, BSC's desire to back out of its agreement to acquire Channel and its bad faith efforts to escape its contractual obligations have nothing to do with anything that occurred at Channel or with the Cerene Device itself—either before or after the execution of the Merger Agreement. Indeed, BSC still stands to acquire a company that is just as valuable

as before with a leading product that holds exactly the same commercial promise as it did when BSC entered into the Merger Agreement. But, whatever its rationale for wanting out of the Merger Agreement, the reasons BSC provided in its May 11, 2018 Letter are entirely lacking in legal basis and BSC is unable to present any valid justification for termination of the parties' agreement.

12. Accordingly, for these reasons and those set forth below, Channel respectfully requests, among other relief, an Order enjoining Defendants from terminating the Merger Agreement and a declaratory judgment that Defendants' purported termination of the Merger Agreement is invalid.

THE PARTIES

13. Plaintiff Channel is a Delaware corporation headquartered in Emeryville, California. Channel is a privately-held medical technology company and the developer of the Cerene Device.

14. Defendant Boston Scientific Corporation is a Delaware corporation headquartered in Marlborough, Massachusetts. Boston Scientific Corporation is a large, publicly traded medical technology company.

15. Defendant NXT Merger Corp. is a Delaware corporation headquartered in Marlborough, Massachusetts and a wholly-owned subsidiary of Defendant Boston Scientific Corporation.

JURISDICTION, VENUE, AND GOVERNING LAW

16. This Court has subject matter jurisdiction over this action pursuant to 8 Del. C. § 111(a)(6) and 10 Del. C. § 341. Pursuant to Section 10.8(a) of the Merger Agreement, the parties consented to jurisdiction in Delaware and "agree[] that all claims in respect of such action or proceeding may be heard and determined exclusively in the Chancery Court of the State of Delaware."

17. Pursuant to Section 10.7 of the Merger Agreement, the parties agreed that the Merger Agreement would be governed by and construed in accordance with Delaware law.

FACTUAL BACKGROUND

The Cerene Device

18. Channel is a privately-held medical technology company that was spun out of the incubator firm TheraNova in 2011 with the purpose of developing technology for endometrial ablation. To that end, Channel developed the Cerene Device, a handheld medical device that uses cryotherapy (application of cold temperature to tissue) to perform endometrial ablation procedures in an office setting.

19. Endometrial ablation is a procedure in which the endometrial lining of the uterine cavity is destroyed so as to reduce monthly endometrial shedding, thereby reducing heavy menstrual flow. The procedure is used to treat

heavy menstrual bleeding ("HMB"), a condition that affects a large portion of premenopausal women and can be a major lifestyle impediment. An estimated 30% of otherwise healthy women of reproductive age report HMB that is substantial enough to disrupt their daily activities.

20. Various methods of endometrial ablation have been developed, most of which require the use of general anesthesia and must be performed in a hospital operating room or ambulatory surgery center. Methodologies currently in use for endometrial ablations involve the use of hot saline, hot steam, plasma energy, or radiofrequency energy in the uterine cavity. All of these methods, including BSC's own competitive hot saline technology, the Genesys HTA System, are painful and therefore require the use of general anesthesia. Additionally, these methods generally require large capital equipment and tend to be somewhat complicated to use, all factors that make office use practically impossible.

21. The Cerene Device offers great commercial promise given its obvious advantages as compared to these competing products. Unlike those products, the Cerene Device uses cold to treat the endometrial lining, an innovation that supports a comfortable treatment in the doctor's office, without the need for general anesthesia. The use of cryothermic (cold) energy makes the treatment more comfortable and is designed to lower the risk of intrauterine scarring and

post-ablation treatment complications that arise following other, heat-based endometrial ablation procedures. The Cerene Device is fully disposable, does not require capital equipment, and is designed to be safe and easy to use. Since the Cerene Device facilitates an in-office procedure, the overall cost of treatment is significantly lower for patients, healthcare providers, and insurers. In short, for treating HMB, the Cerene Device is a game-changer—which is why BSC entered into the Merger Agreement with Channel in November 2017.

The FDA Approval Process

22. On September 13, 2016, the FDA approved an Investigation Device Exemption, which allowed for a clinical study of the Cerene Device, beginning in October 2016. The treatment phase of the CLARITY study, as that clinical study was known, continued until March 2, 2017. During this time, 242 patients—primarily enrolled at eight U.S. sites—were treated for HMB with the Cerene Device. Based on the data generated from the CLARITY study, Channel believes that the Cerene Device was demonstrated to be both safe and effective.

23. On September 8, 2017, Channel submitted an annual progress report to the FDA for CLARITY, indicating that the Cerene Device had a favorable safety profile. Indeed, the CLARITY study showed no serious adverse effects from the device, and the majority of non-serious adverse events were

anticipated for an endometrial ablation procedure. The FDA completed its review of the annual report on October 11, 2017.

24. On July 31 2017, Channel submitted to the FDA what is known as a modular Premarket Approval ("PMA") shell for the Cerene Device. The PMA shell outlines the contents of information and materials to be submitted to the FDA in order to obtain approval to sell a medical device in the U.S. market. According to the FDA's website, the PMA materials include "device description and intended use, nonclinical and clinical studies, case report forms, manufacturing methods, labeling, etc." A modular PMA, as was used here, includes the same basic components except that the materials are divided into separately delineated "modules" and submitted to the FDA on a rolling basis instead of all at once.

25. On August 14, 2017, the FDA agreed to Channel's final modular PMA shell for the Cerene Device, which details the submission of the PMA module and the final PMA between August 2017 and June 2018 and was to consist of the following four modules:

a. Module 1 was to contain: Device Description; Nonclinical Laboratory Studies; and Pre-Clinical (Extirpated) and Clinical (Peri-Hysterectomy and Feasibility) Studies. This module was submitted to the FDA on August 17, 2017.

b. Module 2 was to contain: Nonclinical Laboratory Studies; Software Verification; and Risk Analysis. This module was originally submitted to the FDA on November 22, 2017 and then resubmitted following corrections on May 31, 2018.

c. Module 3 was to contain: Manufacturing and Quality Systems. This module was initially projected for submission on February 16, 2018 and was ultimately submitted on August 13, 2018.

d. Module 4 was to contain: Pivotal Clinical Study; Summary of Safety and Effectiveness Data; and Proposed Labeling. This module was initially projected for submission on June 1, 2018 and was ultimately submitted on August 13, 2018.

26. On August 13, 2018, all four modules for the PMA for the Cerene Device had been submitted to the FDA for approval. On August 28, 2018, the FDA indicated that the PMA had been accepted and contained all necessary elements. On September 6, 2018, following a threshold determination as to the sufficiency of the application (and three weeks in advance of the 45-day regulatory deadline for such a determination), the FDA formally filed the PMA and notified Channel. The FDA's performance goal is to complete its review of the PMA within 180 days of the August 13, 2018 submission. Therefore, assuming the review proceeds in the ordinary course, the FDA's review of the Cerene Device PMA will be completed in the first quarter of 2019.

The Parties' Merger Agreement

27. On November 1, 2017, Channel and BSC entered into the Merger Agreement, by which BSC agreed to acquire Channel. Prior to entering into the Merger Agreement, BSC already had a significant investment in Channel totaling approximately $8 million, or about 15% of Channel's total outstanding equity. With its investments, BSC also had an observer position on Channel's

Board of Directors, which is currently held by Chris Kaster, Vice President of Business Development and Venture Capital Investments for BSC. Per the terms of the Merger Agreement, BSC invested an additional $5.6 million into Channel, increasing its ownership to roughly 20%. With this investment, Mr. Kaster was formally appointed to the Board of Directors.

28. Given that Channel was in the middle of submitting the modular PMA for the Cerene Device in November 2017, and FDA approval had not yet been obtained, the Merger Agreement was designed to protect BSC against the unlikely risk that the Cerene Device would not ultimately be approved by the FDA. To that end, Section 1.1 of the Merger Agreement makes closing contingent upon either BSC exercising its call option or Channel exercising its put option, with the latter effectively preconditioned on FDA approval. Specifically, while BSC can exercise its option at essentially any time, Channel can only exercise its put option during the "Put Period," which is defined in the Merger Agreement to mean the period of 21 days following the FDA's approval of the Cerene Device, provided that the contractually defined "FDA Approval" occurs on or before September 30, 2019, and that the Put Period is to end no later than October 31, 2019.

29. Section 8.1 of the Merger Agreement contains provisions governing termination of the Merger Agreement. In particular, Sections 8.1(f) and

8.1(i) provide bases on which, if satisfied, BSC could terminate the Merger Agreement. As explained in further detail below, neither of these provisions applies here so as to allow BSC to terminate the Merger Agreement.

30. Section 8.1(f)(i) grants BSC a termination right in the event of any inaccuracy or breach by Channel of any representation or warranty in Article III of the Merger Agreement, but only to the extent that the inaccuracy or breach is "such that the condition set forth in Section 7.2(b) would not be satisfied." Section 7.2(b), in turn, states that all representations and warranties are true and correct "except to the extent the failure of any such representations and warranties to be true and correct does not have and would not reasonably be expected to have a Material Adverse Effect" on Channel or BSC. The Merger Agreement defines "Material Adverse Effect" as follows:

> [A]ny change or effect occurring after the Agreement Date that, when taken individually or together with all other adverse changes or effects occurring after the Agreement Date, is materially adverse to the business, results of operations, assets or financial condition of [Channel] or [BSC], as the case may be, and their respective Subsidiaries, taken as a whole, or the ability of [BSC] and Merger Sub to consummate the transactions contemplated by this Agreement . . . .

31. Section 8.1(f)(ii) also grants BSC a termination right in the event of a breach by Channel of any covenant or obligation in the Merger Agreement, but only to the extent "that the condition set forth in Section 7.2(a)

would not be satisfied." Section 7.2(a) in turn states that Channel "shall not have failed to performed [sic] any obligation hereunder in a manner (A) that was willful or intentional and would reasonably be expected to result in material damages to [Channel] or [BSC], or (B) that, together with any other failures to perform obligations hereunder, has resulted in a Material Adverse Effect on [Channel]."

32. Notably, the termination right set forth in Section 8.1(f) is expressly limited by Channel's right to cure. In particular, as to breaches of any representations or warranties existing after the date of the Merger Agreement, Channel has a right to cure any breach to the extent the breach is curable. The relevant proviso in Section 8.1(f) reads:

> [I]f an inaccuracy in or breach of any representation or warranty of [Channel] as of a date subsequent to the date of this Agreement . . . is curable by the same prior to the Termination Date (the "Company Cure Period"), then [BSC] may not terminate this Agreement under this Section 8.1(f) as a result of such inaccuracy or breach prior to the expiration of the Company Cure Period, provided [Channel], during the Company Cure Period, continues to exercise commercially reasonable efforts to cure such inaccuracy or breach . . . .

33. Separately, Section 8.1(i) grants BSC a termination right in the event that "there shall have occurred any Material Adverse Effect with respect to [Channel]."

34. Section 8.1(i) also contains a proviso stating that BSC may not terminate if the MAE is subject to cure and Channel is taking commercially reasonable steps to do just that:

> [I]f the circumstances giving rise to such Material Adverse Event[2] are capable of being ameliorated or cured prior to the Termination Date, then for so long as the party that has experienced a Material Adverse Event continues to exercise commercially reasonable efforts to ameliorate or cure the circumstances giving rise to such Material Adverse Event, this Agreement may not be terminated pursuant to this Section 8.1(i) prior to the Termination Date as a result of the occurrence of such Material Adverse Effect.

35. Finally, Section 10.06 states that the parties "agree that irreparable damage may occur in the event that any provision of this Agreement was not performed in accordance with the terms hereof and that the parties may be entitled to seek specific performance of the terms hereof, in addition to any other remedy at law or equity, without the requirement of posting a bond."

Discovery of Channel Ex-Employee's Misconduct

36. Between December 29, 2017 and January 1, 2018, Channel discovered that its then Vice President of Quality Assurance, Dinesh Shankar, had

[2] While the Merger Agreement does not separately define "Material Adverse Event," it is apparent from the context that this language is meant to refer to an event that has an MAE.

falsified certain expense reports in what Channel came to learn was a fraudulent scheme by which Mr. Shankar was stealing money from Channel.

37. On December 29, 2017, while Channel CEO Ulric Coté and Vice President of Finance Rhonda Bracey were undertaking ordinary year-end housekeeping, they discovered expense reports from Mr. Shankar that appeared to have been signed by Mr. Coté but that he had in fact never seen before. It quickly became apparent that Mr. Shankar had forged Mr. Coté's signature on these reports, which led Mr. Coté and Ms. Bracey to scrutinize the reports and all expenses incurred by Mr. Shankar further. They soon realized that Mr. Shankar had been submitting bills to Channel on behalf of shell companies that he had registered under a single holding company. Over the course of the New Year's weekend, they, along with COO Bill Malecki, discovered several such shell companies. On January 2, 2018, Channel and its corporate counsel, confronted Mr. Shankar with the initial evidence of his wrongdoing, which Mr. Shankar admitted. Mr. Shankar was then placed on leave pending the company's investigation.

38. Immediately upon discovering Mr. Shankar's fraudulent activity, Channel commenced a robust process to rapidly assess the scope of the fraud and to respond appropriately. To start, after notifying the Board of Directors, Channel conducted an internal investigation overseen by counsel at Fenwick &

West LLP, which engaged forensic accountants at Hemming Morse LLP to conduct a financial audit, including a full review of all potentially implicated expense reports. On January 11, 2018, Channel retained Greenleaf Health, Inc. ("Greenleaf"), an FDA regulatory consulting firm, to assess Channel's internal investigation, as well as to do a more general assessment of Channel's overall quality systems. Greenleaf conducted its assessment between February 5 and 8, 2018 and drafted a report dated March 6, 2018, which expressed confidence in the findings from Channel's internal investigation.

39. Through these investigations, Channel discovered that Mr. Shankar had stolen approximately $2.57 million from the company in a fraudulent scheme that began in July 2013. Channel was able to determine that Mr. Shankar had acted alone and that no other Channel employees were involved. Channel learned that Mr. Shankar's scheme involved two elements: submission of invoices from fictitious vendors and submission of falsified expense reports, many of which attached fraudulent supporting invoices and forged signatures.

40. As to the first aspect of his scheme, Mr. Shankar set up six fictitious vendors tied to entities that he created and controlled. He would engage real vendors to perform work that Mr. Shankar paid for on his credit card. He would then prepare and send Channel invoices from the fictitious vendors for amounts higher than what he paid the vendors. Thus, Mr. Shankar would retain the

difference between the actual cost and what Channel paid to his shell companies. This portion of the scheme totaled approximately $2 million.

41. The second aspect of his scheme was based on falsified expense reports accompanied by fabricated invoices for work that was never performed. Again, Mr. Shankar would submit those expenses to Channel for payment to his fictitious shell companies. These false expense reports, to which Mr. Shankar frequently attached forged signatures, totaled approximately $567,000.

42. Channel informed BSC of its initial findings regarding Mr. Shankar's fraudulent conduct on a January 9, 2018 phone call. Channel has kept BSC fully apprised of all material developments since that time.

43. Channel notified the Department of Justice on January 17, 2018 of the facts surrounding Mr. Shankar's fraudulent conduct. On April 12, 2018, Mr. Shankar was indicted on six counts of mail fraud. The criminal proceedings are ongoing.

44. While all of the evidence indicates that Mr. Shankar's motivation was purely financial in nature, he needed to falsify certain related documents in order to avoid detection and make the documentary record support the fraudulent invoices and expense reports he was submitting to Channel. For example, in some instances Mr. Shankar charged Channel for tests that were never actually performed. So, to support that fraudulent charge, he would take a report

reflecting a prior instance of testing and modify the date and certain other information such that the report appeared to reflect the test for which Channel was charged, even though that test was never actually performed. Through its investigation, Channel discovered that certain of these falsified reports were included in submissions to the FDA with certain of the PMA modules for the Cerene Device.

45. The company and its independent consultants completed a thorough risk assessment and determined that the majority of reports Mr. Shankar falsified had no safety-related implications. With respect to three of Shankar's falsified reports, however, Channel believed there were potential issues related to safety controls: (1) alterations to natural bioburden test results, including fabrication of bacteriostasis/fungistasis testing data and removal of recommendations for further testing; (2) fabrication of a sterile package gross leak detection and seal strength report; and (3) fabrication of radiated emissions tests. Accordingly, Channel engaged independent experts and completed additional testing and review of data to ensure that each of those tests was properly conducted and that there are no safety concerns arising out of Mr. Shankar's fraudulent conduct.

46. Critically, nothing Mr. Shankar did affected the CLARITY study or any of the data gathered thereunder in any way whatsoever. Mr. Shankar

did not have access to the data for the CLARITY study. Therefore, the key clinical data regarding the safety and efficacy of the Cerene Device is wholly unaffected by Mr. Shankar's fraudulent conduct.

47. Channel has taken remedial efforts to correct for Mr. Shankar's misconduct, including through the creation of Internal Audit Reports ("IARs") containing detailed risk assessments for each of the discrepancies identified between the accurate and falsified reports. Overall, the IARs contain fourteen categories, each of which describes the problem and contains a root cause analysis, risk assessment, and a correction plan. Each correction plan was assigned a due date for internal resolution. Thirteen of the correction plans have now been completed with the submission of the PMA, and the last plan will be completed with revisions to the Investigation Device Exemption in September 2018. The IARs have been subsequently reviewed in a June 2018 audit by independent health care advisors at Greenleaf, which expressed satisfaction with the Company's remediation efforts.

Discussions with FDA Following Disclosure of Employee Misconduct

48. Channel has been and is continuing to be fully forthcoming with the FDA regarding Mr. Shankar's fraudulent conduct. As a result of Channel's transparency and proactive approach to dealing with the problem, Channel has succeeded in working with the FDA to promptly resolve all of the

potential problem areas affecting Channel's PMA submission with the result that there will be no material delay to the overall approval process. The process for FDA approval of the Cerene Device PMA remains on track to be completed within the period contemplated under the Merger Agreement.

49. On January 22, 2018, Channel reached out to officials at the FDA to request a phone call. That call took place a few days later on January 25, 2018, and Channel provided the FDA with a high-level overview of the facts surrounding Mr. Shankar's fraudulent conduct. During that call, Channel asked for an opportunity to meet with the FDA in person in order to provide a more detailed presentation concerning what it had learned and what it was doing to respond, a meeting ultimately scheduled for March 16, 2018. By the time of this January 25 call, Channel had already submitted Modules 1 and 2 of the Cerene Device PMA. During the call, the FDA asked Channel to withdraw Module 2, which Channel did on February 14, 2018. As noted above, Channel resubmitted Module 2 on May 31, 2018 after correcting for inaccuracies that had been included in the submission as a result of Mr. Shankar's fabrication of certain documents.

50. On March 16, 2018, members of Channel's executive leadership team and ex-FDA officials from Greenleaf, [redacted], met with the FDA. During the course of the March 16 meeting, along with

answering questions from the FDA, representatives for Channel provided background on the company, the Cerene Device, the findings from the investigations, and the remedial actions the company had taken or planned to take. Among other things, the FDA asked Channel to resubmit any tests affected by Mr. Shankar's fraud that had been included in Modules 1 and 2, as well as to amend the Investigation Device Exemption with the corrected reports where applicable. Channel agreed and proceeded to provide all requested updates. Channel also proposed certain changes to the modular PMA plan. [redacted]

51. Following up on the March 16 meeting, Channel held a call with the FDA on April 18, 2018. During that call, Channel and the FDA agreed that Channel would resubmit Module 2 in May 2018 and that the remaining modules, including the data from the CLARITY study, would be submitted by August 2018. [redacted]

52. As noted above, Channel proceeded to resubmit Module 2 on May 31, 2018 and Modules 3 and 4 on August 13, 2018. Channel has kept BSC fully apprised of all of these developments and discussions with the FDA.

53. As of now, there is no reason to expect that the FDA will not approve the PMA application for the Cerene Device by September 30, 2019, as required under the Merger Agreement in order to trigger Channel's put option.

BSC's Improper Attempt to Back Out of the Merger Agreement

54. On May 11, 2018, BSC sent Channel a letter purporting to declare void or otherwise terminate the Merger Agreement. This letter came four months after Channel had informed BSC of the key facts, and weeks after Channel's highly productive interactions with the FDA. With its letter, BSC made clear that it was repudiating its contractual obligations under the Merger Agreement. Because it had no valid basis on which to do so, BSC has been in breach of the Merger Agreement since that time.

55. In its May 11 letter, BSC articulated two misguided theories in an attempt to back out of the Merger Agreement. *First*, BSC claimed that it was fraudulently induced to enter the Merger Agreement as a result of misleading statements regarding Channel's progress toward FDA approval and compliance with FDA regulations. *Second*, BSC further purported to terminate the Merger Agreement pursuant to Section 8.1(f), based on alleged breaches of various

representations and warranties in the Merger Agreement, and Section 8.1(i), based on a purported MAE. As discussed below, neither argument justifies termination of the Merger Agreement.

A. *BSC May Not Declare the Merger Agreement Void Based on Its Claim of Fraudulent Inducement.*

56. BSC has no basis on which to claim that it was fraudulently induced to enter the Merger Agreement. BSC wrongly claims that Mr. Shankar's knowledge that certain documents submitted to the FDA were falsified somehow can be imputed to Channel, the very entity that he defrauded and stole from. To the contrary, under black letter law (and as Channel has advised BSC), Mr. Shankar's knowledge is not imputed to Channel because he was acting solely to advance his own interests and in total abandonment of Channel's interests. Mr. Shankar's scheme was intended only to enrich himself at Channel's expense. Moreover, the Merger Agreement contains express terms concerning whose individual knowledge is imputed to Channel (Mr. Coté, Mr. Malecki, or Ms. Bracey, or any of their successors), and, significantly, Mr. Shankar is not included in that list. And, even if Mr. Shankar's knowledge and intent could be imputed to Channel (and they cannot), BSC still would not be able to establish the basic elements of a claim for fraudulent inducement.

57. For example, there is absolutely no reason to believe that Mr. Shankar intended to induce BSC to take or refrain from taking any action,

including entering into the Merger Agreement. Everything that Channel has learned through its investigation of Mr. Shankar's conduct—all of which has been shared with BSC—indicates that his actions were part of a personal scheme to steal money from Channel to enrich himself. Mr. Shankar falsified and inflated invoices for vendor expenses in order to funnel overpayments from Channel to shell companies he created. He then falsified related reports and documents in order to cover his tracks. All of this was done to defraud Channel and enrich Mr. Shankar. There is no reason whatsoever to believe Mr. Shankar intended to separately defraud BSC or that he even contemplated whether or how his scheme might impact BSC's acquisition of Channel.

58. Nor can BSC show justifiable reliance because Section 4.6 of the Merger Agreement expressly states that BSC is not relying on any representations outside the Merger Agreement: "[BSC] is not relying and has not relied on any express or implied representations or warranties of any nature (including as to the accuracy or completeness of any information provided to [BSC]) made by or on behalf of, or imputed to [Channel], except as set forth in this Agreement."

59. Moreover, as a major investor in Channel, BSC had extensive access to information within Channel's possession even before the Merger

Agreement, and it never once raised any issues pertaining to Mr. Shankar or called into questions any of the quality control practices BSC now criticizes.

60. Finally, BSC also cannot show it suffered damages attributable to any purported fraud, let alone damages sufficient to void the Merger Agreement, since the FDA approval process for the Cerene Device remains on track, and there is every reason to believe it will be approved within the timeframe contemplated by the parties.

61. In sum, Defendants cannot terminate the Merger Agreement based on any claim of fraudulent inducement.

B. *BSC Has No Basis on Which to Terminate the Merger Agreement Based Upon a Purported MAE or Alleged Breaches of Representations and Warranties or Covenants.*

62. BSC similarly does not have grounds for termination under Section 8.1(f) or 8.1(i) of the Merger Agreement.

63. As noted above, Section 8.1(i) provides a termination right in the event that there is a "Material Adverse Effect." No MAE has occurred or is reasonably likely to occur here.

64. There is no reason to expect that Mr. Shankar's wrongful conduct substantially threatens Channel's earnings potential, let alone in a durationally-significant manner, as is required to establish an MAE. There is every reason to believe that the approval process for the Cerene Device remains on track

and, as such, nothing related to Mr. Shankar's misconduct, either alone or in the aggregate, materially impacts Channel or its business as a whole.

65. Moreover, Section 8.1(i) states that BSC may not terminate if the MAE is subject to cure and Channel is taking commercially reasonable steps to do so. In this case, the inaccuracies in Channel's submission to the FDA, even if they did amount to an MAE (and they do not and cannot), are plainly capable of cure. Indeed, as soon as Channel learned of the issue, it alerted the FDA and began working toward curing the issue. As noted above, [redacted], and the approval process for the Cerene Device remains on track.

66. Nor is there any basis for termination under Section 8.1(f) of the Merger Agreement. Section 8.1(f)(i) provides a limited termination right where Channel has breached its representations and warranties and such breach has or would reasonably be expected to have an MAE. Section 8.1(f)(ii) provides a limited termination right based on Channel's breach of one or more covenants or obligations in the Merger Agreement, if the breach either (1) is "willful or intentional" and "would reasonably be expected to result in material damages to [Channel] or [BSC]," or (2) has "resulted in a Material Adverse Effect on [Channel]."

67. *First*, Section 8.1(f)(i) does not apply because, as a preliminary matter, Channel has not breached any representations and warranties, including those that BSC has cited in correspondence between the parties: Sections 3.18(b), 3.18(c), 3.22(a), 3,22(c), 3.22(f), and 3.22(h).

68. Section 3.18(b) states in part that Channel "has at all times been in possession of all permits, licenses, franchises, approvals, authorizations, registrations, clearances, and exemptions ('Permits') necessary for it to . . . carry on its business as it is now being conducted" and that neither Channel nor anyone acting on its behalf "is or has been in material breach or violation of any Permit of [Channel] to operate its business." Contrary to BSC's assertions, that representation is true.

69. Section 3.18(c) states in part that all materials "utilized as the basis for or submitted in connection with any and all requests for a Permit relating to the Products or the Company Business, when submitted to the relevant Governmental Authority were true, complete and correct ***in all material respects*** as of the date of submission and any necessary or required updates, changes, corrections or modifications to such applications, submissions, information and data have been submitted to the relevant Governmental Authority" (emphasis added). That representation is true. While, as discussed above, there were certain inaccuracies in Channel's submissions to the FDA, those inaccuracies were

immaterial since they did not bear upon the safety or efficacy of the Cerene Device.

70. Section 3.22(a) states in part that "[t]he design, manufacture, testing, and distribution of the Products by or on behalf of the Company and its Subsidiaries is being conducted in compliance with all applicable Healthcare Laws." That representation is true, and BSC has not pointed to (and, indeed, cannot rightly point to) any law within the definition of "Healthcare Laws" that Channel has violated.

71. Section 3.22(c) states in part that "[a]ll applications, notifications, submissions, information, claims, reports, and filings utilized as the basis for or submitted in connection with any and all requests for a Company License from the FDA or other Governmental Authority relating to the Products, when submitted to the FDA or any other Governmental Authority, were true, accurate and complete ***in all material respects*** as of the date of submission" (emphasis added). That representation is true. As with the representation in Section 3.18(c), there were certain inaccuracies in Channel's FDA submissions, but those inaccuracies were immaterial since they did not bear upon the safety or efficacy of the Cerene Device.

72. Section 3.22(f) states in part that "[a]ll preclinical and clinical trials . . . that have been or are being conducted by or on behalf of, or sponsored

by, the Company . . . were and, if still pending, are being or have been conducted in compliance ***in all material respects*** with standard medical and scientific research procedures and the experimental protocols, procedures and controls pursuant to applicable Healthcare Laws" (emphasis added). This representation is true, once again because any deviations did not affect safety or efficacy and therefore were immaterial.

73. Section 3.22(h) states in part that "[n]either the Company nor any of its Subsidiaries . . . has made any untrue statement of material fact to the FDA or any Governmental Authority, failed to disclose a material fact required to be disclosed to the FDA or any Governmental Authority, or committed an act, made a statement or failed to make a statement that, at the time such disclosure was made, would reasonably be expected to provide a basis for the FDA or any other Governmental Authority to invoke the FDA Fraud Policy or any similar policy." This representation is true. While there were certain inaccuracies in Channel's FDA submissions, those inaccuracies were not fraudulent since Channel was unaware of their existence. Indeed, not only did Channel have no intent to defraud the FDA, it went above and beyond to promptly remedy the inaccuracies as soon as they were discovered.

74. Moreover, even if there were one or more breaches, for the same reasons set forth above, any such purported breaches would not individually or in the aggregate constitute an MAE.

75. Nor can BSC rely upon Section 8.1(f)(ii), which applies to certain breaches of covenants and obligations. In correspondence between the parties, BSC has alleged that Channel breached its obligation in Section 5.2 of the Merger Agreement to "use commercially reasonable efforts to diligently conduct and complete all research and development activities with respect to the Company Products in compliance with all applicable Laws." In fact, Channel has fully complied with this obligation at all times. For the reasons set forth above, Mr. Shankar's conduct—of which Channel was the victim—cannot be attributed to Channel. The company itself has at all times used commercially reasonable efforts to conduct its affairs in a manner that is consistent with all legal requirements, including as it relates to its research and development work. Moreover, even if BSC could show a breach, it would not be able to show, as required under Section 7.2(a), that such a breach was either "willful or intentional and would reasonably be expected to result in material damages" or resulted in an MAE.

76. Further, as with Section 8.1(i), Section 8.1(f) contains a proviso stating that BSC may not terminate if the MAE is subject to cure and Channel is

taking commercially reasonable steps to do so. That is precisely, as discussed above, what Channel is doing and has done here.

The Parties' Settlement Efforts

77. Since receiving BSC's May 11, 2018 letter, the parties have engaged in efforts to resolve this dispute. To that end, representatives of the parties have exchanged correspondence, engaged in telephone calls, and, on August 15, 2018, conducted an in-person meeting in which Channel provided BSC with information relevant to the dispute.

78. Those efforts have been unsuccessful. On August 27, 2018, BSC informed Channel by letter that its position remained unchanged, namely, that BSC still contended that the Merger Agreement was terminated for the reasons stated in its May 11, 2018 letter.

BSC's Unjustified Termination Would Harm Channel If Permitted

79. Channel will undoubtedly suffer harm if BSC is permitted to terminate the Merger Agreement. Most obviously, Channel and its investors will not receive the monetary consideration to be paid upon closing of the Transaction, and will suffer other harms as well.

80. To the extent the Transaction with BSC falls apart, Channel faces the serious risk of unwarranted reputational harm in the market. Channel also faces the loss of employees and the unwarranted loss of confidence from

investors and customers, as well as from contractual counterparties such as suppliers and vendors. The Cerene Device also risks serious impairment in the marketplace if BSC is permitted to terminate since the plans for marketing and distribution of the Cerene Device have been developed with the expectation that, in partnering with BSC, Channel would benefit from BSC's extensive experience and expertise in marketing medical devices.

81. During negotiations with BSC, Channel agreed, despite its preference against doing so, to move its manufacturing from in-house to a third party. As a result, Channel spent approximately $2 million to accommodate BSC's request. In addition to that financial hardship, BSC has restricted Channel's ability to run its business and to direct resources toward the most efficient use in the manner that Channel would have done but for the constraints imposed under the Merger Agreement. If the Transaction is not consummated, Channel will have unnecessarily expended its money and efforts.

82. Further, in the course of discussions pertaining to the combination of the two companies, BSC has become privy to commercially sensitive information from Channel, such that BSC would be unjustly enriched and Channel unfairly disadvantaged as a result of BSC learning critical details about Channel's innovative technology and business. Channel never would have disclosed such information if it believed BSC would fail to act in good faith to

consummate the Transaction. That is particularly true given that BSC owns a product that would be in direct competition with the Cerene Device, the Genesys HTA System.

83. Finally, relying on BSC's promise as embodied in the Merger Agreement, Channel has pushed forward with its plans to merge with BSC when it otherwise could have been pursuing other strategic partners. BSC's offer was intended to preempt those discussions and take Channel off the market. Therefore, Channel will have been harmed as a result of being taken off the market for a period of time.

84. In contemplation of the full range of harms that Channel could face if BSC were to breach the contract, the parties expressly agreed in Section 10.6 of the Merger Agreement that specific performance would be available as a remedy for breaches of the Merger Agreement.

FIRST CAUSE OF ACTION
(Breach of Contract)

85. Channel repeats and realleges the allegations in the foregoing paragraphs as though fully set forth herein.

86. The Merger Agreement is a valid and binding contract between Channel and BSC.

87. Channel has fully performed all of its obligations required by the Merger Agreement.

88. Under Section 6.03(b) of the Merger Agreement, BSC was required to "take all further action that is necessary or desirable to carry out the purposes of this [Merger] Agreement" and was required to "use its commercially reasonable efforts to take all such action and . . . [to] refrain from taking any actions which would be reasonably expected to frustrate the essential purposes of, the transactions contemplated by this [Merger] Agreement, if . . . [Channel] were to deliver a Put Option Election Notice."

89. BSC has materially breached the Merger Agreement, including but not limited to its obligations under Section 6.03(b) of the Merger Agreement, by declaring its intention to cease performing its obligations thereunder and to terminate the Merger Agreement without a valid basis.

90. BSC expressly agreed in Section 10.06 of the Merger Agreement to the remedy of specific performance in the event of any breach of the Merger Agreement.

91. BSC's material breaches of the Merger Agreement threaten to prevent Channel and its stockholders from receiving the benefit of the parties' bargain, which would result in irreparable harm to Channel and its stockholders. Consequently, Channel is entitled to an Order preventing BSC from avoiding its clear obligations under the Merger Agreement.

92. Channel has no adequate remedy at law.

SECOND CAUSE OF ACTION
(Declaratory Judgment)

93. Channel repeats and realleges the allegations in the foregoing paragraphs as though fully set forth herein.

94. No MAE has occurred.

95. Because no MAE has occurred, the closing condition under Section 7.2(c) of the Merger Agreement is satisfied.

96. Channel has not breached, and has complied in all material respects with, its covenants under the Merger Agreement.

97. Because Channel has not failed to perform any obligation under the Merger Agreement "in a manner (A) that was willful or intentional and would reasonably be expected to result in material damages to the Company or Parent, or (B) that, together with any other failures to perform obligations hereunder, has resulted in a Material Adverse Effect on the Company," the closing condition under Section 7.2(a) of the Merger Agreement is satisfied.

98. Channel has not breached its representations and warranties under the Merger Agreement. Moreover, none of Channel's alleged breaches of its representations and warranties provide any basis for BSC to terminate the Merger Agreement because such alleged breaches "do[] not have and would not reasonably be expected to have a Material Adverse Effect," thus defeating any grounds for termination based upon Section 7.2(b) of the Merger Agreement.

99. BSC may not terminate the Merger Agreement based upon any purported MAE or any purported failure by Channel to comply in all material respects with its covenants under the Merger Agreement, or on any alternative basis.

100. BSC has no right to terminate the Merger Agreement and is not excused from performing its obligations under the Merger Agreement.

101. Pursuant to 10 Del. C. § 6501 and Court of Chancery Rule 57, Channel requests a declaratory judgment that: (i) BSC has breached its obligations under the Merger Agreement, specifically including its obligations under Section 6.03 of the Merger Agreement; (ii) nothing has had or would reasonably be expected to have an MAE; (iii) Channel has not breached, and has complied in all material respects with, its covenants under the Merger Agreement; (iv) Channel has not breached its representations and warranties under the Merger Agreement, and none of the purported breaches of representations and warranties alleged by BSC would reasonably be expected to have an MAE; and (v) BSC has no right to terminate the Merger Agreement and is not excused from performing its obligations under the Merger Agreement.

PRAYER FOR RELIEF

WHEREFORE, Channel respectfully requests that the Court:

a. declare that the Merger Agreement remains in full force, that BSC may not terminate the Merger Agreement and has no basis on which to terminate the Merger Agreement, and that BSC has itself committed material breaches of the Merger Agreement;

b. order BSC to specifically perform its obligations under the Merger Agreement, including its obligations under Section 6.03(b) of the Merger Agreement and to close on the Transaction in the event that Channel exercises its put option following FDA approval;

c. award Channel damages, in an amount to be proven in a subsequent proceeding;

d. award Channel pre-judgment and post-judgment interest on its damages and its costs and expenses incurred in connection with this lawsuit, including expert fees and reasonable attorneys' fees; and

e. grant Channel such other and further relief as may be just and proper.

PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP

By: */s/ Daniel A. Mason*
Stephen P. Lamb (#2053)
Daniel A. Mason (#5206)
500 Delaware Avenue, Suite 200
Post Office Box 32
Wilmington, DE 19899-0032
(302) 655-4410

OF COUNSEL:

Andrew G. Gordon
Jaren Janghorbani
Andrew J. Markquart
PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019-6064
(212) 373-3000

MORRIS, NICHOLS,
ARSHT & TUNNELL LLP

By: */s/ William M. Lafferty*
William M. Lafferty (#2755)
Thomas W. Briggs, Jr. (#4076)
Richard Li (#6051)
1201 North Market Street
Wilmington, DE 19801
(302) 659-9200

Dated: September 12, 2018

Attorneys for Plaintiff
Channel Medsystems, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on September 17, 2018, the foregoing was caused to be served upon the following counsel of record via File and Serve*Xpress*:

Via First Class Mail
Boston Scientific Corporation
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

Via First Class Mail
NXT Merger Corp.
c/o Corporation Service Company
251 Little Falls Drive
Wilmington, DE 19808

/s/ Richard Li
Richard Li (#6051)