
The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Abbott Laboratories (“Abbott”) of

- F. “Acquisition” means Abbott’s acquisition of St. Jude through a series of transactions as contemplated by and pursuant to the Agreement and Plan of Merger dated April 27, 2016, among Abbott Laboratories, St. Jude Medical, Inc., Vault Merger Sub, Inc., and Vault Merger Sub LLC that was submitted by the Respondents to the Commission.
- G. “Acquisition Date” means the date on which the Acquisition is consummated.
- H. “ACT” means Advanced Cardiac Therapeutics, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 22880 Lakeside Drive, Suite 250, Santa Clara, CA 95054.
- I. “Agency(ies)” means any governmental regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s) or permit(s) for any aspect of the research, development, manufacture, marketing, distribution or sale of Vascular Closure Devices or Steerable Sheaths. The term “Agency” includes, but is not limited to, the United States Food and Drug Administration (“FDA”).
- J. “Application(s)” means all submissions and applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Parts 800 to 898, including all premarket notifications (Section 510(k) submissions) and premarket approvals (“PMA”), and all supplements, amendments, and revisions thereto, any preparatory work, registration dossier, drafts and data necessary for the preparation thereof, and all correspondence between the holder and the FDA related thereto.
- K. “Assets To Be Divested” means the VCD Assets To Be Divested and the Steerable Sheath Assets To Be Divested.
- L. “Business” means the research, development, manufacture, commercialization, distribution, marketing, promotion, importation, exportation, advertisement, and/or sale of a Product.
- M. “Business Records” means all books, records, files, databases, printouts, and all other documents of any kind, whether stored or maintained in hard copy paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media, including, without limitation: customer files, customer lists, customer purchasing histories, supplier and vendor files, vendor lists, correspondence, advertising and marketing materials, marketing analyses, sales materials, price lists, cost information, employee lists and contracts, salary and benefits information, personnel files, financial and accounting records and documents, financial statements, financial plans and forecasts, operating plans, studies, reports, regulatory materials, Applications, Agency filings and submissions, Agency correspondence, operating guides, technical information, manuals, policies and procedures, service and warranty records, maintenance logs, equipment logs, registrations, and permits.
- N. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

- O. “Closing Date(s)” means the date(s) on which Respondents (or a Divestiture Trustee) consummate a transaction to divest any of the Assets To Be Divested to an Acquirer(s) pursuant to this Order.

reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA or any other Agency.

- S. “Direct Cost” means a cost not to exceed the cost of labor, material, travel, and other expenditures to the extent such costs are directly incurred to provide the relevant Product(s), inputs, components, goods, assistance or services. “Direct Cost” to the Acquirer(s) for its use of any of Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee;

Provided, however, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order; and (ii) an agreement becomes a Remedial Agreement for the Assets to be Divested, “Direct Cost” means such cost as is provided in such Remedial Agreement.

- T. “Divestiture Trustee” means any Person appointed by the Commission pursuant to Paragraph IV of this Order.

- U. “Employee(s)” means:

1. If Terumo is approved by the Commission to be the Acquirer, the employees identified in the Terumo Purchase Agreement; or
2. If the Acquirer(s) is not Terumo, any individual employed on a full-time, part-time, or contract basis as of, and at any time after, April 28, 2016, the date of the announcement of the Acquisition, by:
 - a. St. Jude, where such employee’s job responsibilities relate or related primarily to the VCD Business; and
 - b. Abbott (or Kalila), where such employee’s job responsibilities relate or related primarily to the Steerable Sheath Business.

- U. “Facility Assets” means all of Respondents’ rights, title, and interests in and to the following:

1. All real property interests, including all rights, title, and interests in and to owned or leased property, together with all easements, rights of way, buildings, improvements, and appurtenances (“Facility(ies)”);
2. All applicable federal, state, and local regulatory registrations, permits, and applications, and all documents related thereto, necessary for the operation and conduct of the Relevant Business at such Facility(ies) to the extent held by Respondents and with respect to which the transfer thereof is permitted by law; *provided, however,* that Respondents shall cooperate with the Acquirer in securing any federal, state, and local regulatory registrations, permits, and applications for which transfer is not permitted by law; and
3. All fixtures, equipment, machinery, tools, molds, dies, vehicles, personal property, or tangible property of any kind located at such Facility(ies) that are owned or leased by

Respondents, or that Respondents have the legal right to use, or over which they have custody or control, that are related to:

- a. The research, development, production, manufacture, marketing, or sale of any Product related to the Relevant Business; or
- b. Compliance with any statute, ordinance, regulation, rule, or other legal requirement (including, but not limited to, environmental laws) of any Government Entity.

V. “Governmental Entity” means any federal, state, local or non-U.S. government or any court, legislature, governmental Agency or governmental commission or any judicial or regulatory authority of any government.

W. “Intellectual Property” means all intellectual property related to the Product(s) that is owned, licensed, or controlled by the Respondents as of the Closing Date, and all associated rights thereto, including all of the following in any jurisdiction throughout the world: (i) all Patents; (ii) all Trade Secrets; (iii) all Know-How; (iv) all Trademarks; (v) all Trade Dress; (vi) all Copyrights; (vii) all computer software (including source code, executable code, data, databases, and related documentation); (viii) all Marketing Materials; and (ix) all rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, misuse, violation, or breach of any of the foregoing.

X. “Inventories” means:

1. All inventories, stores, and supplies of any semi-finished and finished Product(s) and work in progress; and
2. All inventories, stores, and supplies of raw materials and other materials relating to the research, development, manufacture, finishing, packaging, labeling, distribution, marketing, or sale of any Product(s).

Y. “Kalila” means Kalila Medical, Inc., a Delaware corporation engaged in the Business of Steerable Sheath Products. A Bi(Body(h P)t a)-1(nd)]tquir Sal21(1)-2(e(a)0.9(teh P)od)5(e)001 Tc -0.001.ee

Z. “Kalila Acquisition” means the a P.9(n)2(g)tn of Merger, dat SJanuary 29, 20nd among A Bi(Bod7(h P)t L)1(a)-1(bor)-2(a)4(t)-2(or)-2(i)3(e)-1 . hf.15(h)1((at)1(yi)-2(ngTA)2(-1(nga)-1(ge1(r)-2)4(t)3()-1()-19(ean)1(s s L)1(agoodw)(oe)-1(s)-1s)-1)-1(t)3[

BB. “Law” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law by any Governmental Entity.

CC. “Manufacturing Technology and Equipment” means all technology and equipment to make a Product, including, but not limited to:

1. All technology, Trade Secrets, Know-How, formulas, and proprietary information (whether patented, patentable, or otherwise) related to the manufacture of a Product, including, but not limited to, all of the following: product specifications; processes; analytical methods; product designs; plans; ideas; concepts; manufacturing, engineering, and other manuals and drawings; standard operating procedures; flow diagrams; quality assurance and quality control systems; research records; clinical data; compositions; annual product reviews; regulatory communications; control history; current and historical information associated with FDA Application(s) conformance and cGMP compliance; labeling and all other information related to the manufacturing process; and supplier lists;
2. All ingredients, materials, or components used in the manufacture of a Product; and
3. All machinery, equipment, mechanical and spare parts, supplies, tools, tooling, jigs, molds, dies, production supplies, samples, media, and fixtures used to manufacture, fin -15.215 -5n thi2f 1 en,

5. All Product Approvals;

6.

- VV. “Steerable Sheath Business” means the Business of Abbott relating to the Steerable Sheath Products acquired in the Kalila Acquisition, as conducted and maintained by Abbott since the Kalila Acquisition, including without limitation all improvements and activities relating thereto as of the Closing Date.
- WW. “Steerable Sheath Products” means the Steerable Sheaths and any related Products acquired by Abbott in the Kalila Acquisition, including all Products marketed or sold under the following Trademarks: Vado® 1.0, Vado® 1.1, and Vado® 2.1.
- XX.

5. All Product Approvals;
6. All Marketing Materials;
7. The Puerto Rico Facility and all Facility Assets related thereto; *provided, however*, that this includes only the portion of the lease agreement between Respondents and the Puerto Rico Industrial Development Company applicable to the Puerto Rico Facility;
8. All Contracts related to the Puerto Rico Facility;
9. All Contracts related to the research, development, manufacture, marketing, sale, and distribution of VCD Products and VCD Components at the Minnesota Facility, in each case only to the extent they are related to, and only upon completion of Respondents' obligations under, any Transitional Manufacturing and Supply Agreement for the supply of VCD Products and VCD Components to the Acquirer;
10. All Inventories related to the Puerto Rico Facility; and
11. All Business Records;

Provided, however, that:

- a. "VCD Assets To Be Divested" do not include (1) the Retained Products or the Retained Business(es); and (2) any part of the VCD Assets to Be Divested if not needed by an Acquirer and the Commission approves the divestiture without such assets;
- b. "Intellectual Property" does not include: (i) the corporate names or corporate Trade Dress of Respondents or the related corporate logos thereof, or the corporate names or corporate Trade Dress of any other corporations or companies owned or controlled by the Respondents or the related corporate logos thereof, or general registered images or symbols by which Respondents can be identified or defined; or (ii) the business marks specified on Schedule 5.07(a) of the Terumo Purchase Agreement; and
- c. Where Respondents' Business Records contain information: (i) that relates both to the Assets to be Divested and to Retained Products or Retained Business(es) and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Assets to be Divested; or (ii) for which the Respondents have a legal obligation to retain the original copies, Respondents shall be required to provide only copies or relevant excerpts of, or access to, the relevant Business Records containing this information. In instances where such copies are provided to the Acquirer, Respondents shall provide the Acquirer with access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this provision is to ensure that the Respondents provide the Acquirer with the above-described information without requiring the Respondents completely to divest

B. Prior to the Closing Date, Respondents shall:

1. Secure, at their sole expense, all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Assets To Be Divested to the Acquirer(s), and to permit the Acquirer(s) to continue to operate the Businesses related to the Assets To Be Divested in a manner that will achieve the purposes of this Order; *provided, however*, that the Respondents may satisfy this requirement by certifying that the Acquirer(s) has executed agreements or entered into equivalent arrangements directly with the relevant Third Party(ies); and
2. Secure the transfer from the Respondents to the Acquirer(s) of any licenses, approvals, permits, registrations, certificates, rights, or other authorizations from any Persons or Governmental Entity(ies) that are necessary to accomplish the divestiture and transfer of the Assets To Be Divested to the Acquirer(s), and for the continued operation of such assets by the Acquirer(s), in a manner that will achieve the purposes of this Order;

Provided, however, that in the event Respondents are unable to secure the transfer to the Acquirer(s) of, or the Acquirer is unable to obtain, any license(s), approval(s), permits(s), registration(s), certificate(s), right(s), or authorization(s) with respect to the VCD Assets To Be Divested in any of the “Specified Jurisdictions” identified in the Terum2.1(y)2(tif)5(ie.9(n)2(s)1(eTw

the Acquirer's request, Respondents shall file with the Commission any request for prior approval to extend the term of a Transition Services Agreement as provided in this Paragraph. The Transition Services provided pursuant to a Transition Services Agreement shall be at no greater than Respondents' Direct Costs for such personnel, technical support, assistance, training, and other services as are necessary to transfer the Assets To Be Divested to the Acquirer and enab

5. Not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except (i) the Acquirer, (ii) other Persons specifically authorized by the Acquirer to receive such information, (iii) the Commission, and (iv) the Monitor, if any, and the Divestiture Trustee, if any; and

6. No later than thirty (30) days after the Closing Date, provide written notification of the restrictions on the use of the Confidential Business Information to all Respondents' employees who are involved in the manufacture, distribution, sale, or marketing of the Assets to be Divested or who may have or have access to Confidential Business Information ("Designated Employees"); Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for at least one year, if any, after the Closing Date.

- b. Specific description of the employee's responsibilities and primary work location;
- c. The base salary or current wages;
- d. Most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year, current target or guaranteed annual bonus or commission opportunities and target long term incentive opportunities, if applicable;
- e.

- b. Hire Employees who apply for employment with Respondents, as long as such Employees were not solicited by Respondents in violation of this Paragraph II.F.

Provided, however, that this Paragraph II.F. shall not prohibit Respondents from making offers of employment to or employing any Employee after the Closing Date where: (i) the Acquirer has notified Respondents in writing that the Acquirer does not intend to make an offer of employment to that Employee; (ii) the Acquirer has terminated the employment of the Employee; or (iii) where the Employee's employment with the Acquirer ended for any reason more than ninety (90) days prior to Respondents' solicitation of the Employee.

- G. Pending divestiture of the Assets To Be Divested, Respondents shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Assets To Be Divested, and to prevent the destruction, removal, deterioration, or impairment of any of the Assets To Be Divested.
- H. The purpose of the divestiture of the Assets To Be Divested is to ensure the continued use of the assets in the same Businesses in which the Assets To Be Divested were engaged at the time of the announcement of the proposed Acquisition by Respondents and to remedy the lessening of competition alleged in the Commission's complaint.

III.

IT IS FURTHER ORDERED that:

- A. Edward J. Buthusiem shall serve as Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreement, including any Transition Services Agreement and Transitional Manufacturing and Supply Agreement, approved by the Commission.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
 3. The Monitor shall serve for such time as is necessary to monitor Respondents' compliance with the provisions of the Orders and the Remedial Agreement, including for as long as Respondents are providing Transition Services to the Acquirer pursuant to a Transition Services Agreement or supplying VCD Products or VCD Components to the Acquirer pursuant to a Transitional Manufacturing and Supply Agreement; *provided, however*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;
 4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under the Orders and the Remedial Agreement. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders and the Remedial Agreement;
 5. The Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
 6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Monitor; and
 7. Respondents shall report to the Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under this Order or the Remedial Agreement. Within thirty (30) days after the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Orders.
- C. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.

D. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

E.

any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

- C. No later than ten (10) Days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture(s) required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets or rights that are required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by this Order;
 2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture(s), which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court-appointed Divestiture Trustee, by the court; *provided, however*, the Commission may extend the divestiture period only two (2) times;
 3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by the Order, or to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture(s). Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court;
 4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in the contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture(s) shall be made in the manner and to an acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for any of the Assets to be Divested, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further* that Respondents shall select such entity within five (5) days after receiving notification of the Commission's approval;

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or

G. The Commission, or in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture(s) required by this Order.

V.

IT IS FURTHER ORDERED that, for a period of ten (10) years from the date this Order is issued, Respondents shall not, acquire, directly or indirectly, through subsidiaries or otherwise, any ownership, leasehold, or other interest, in whole or in part, in ACT or the assets of the ACT, without providing advance written notice to the Commission.

The prior notification required by this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the “Notification”), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification; Notification shall be filed with the Secretary of the Commission; Notification need not be made to the Department of Justice; and Notification is required only of the Respondents and not of any other party to the transaction. Respondents shall provide two (2) complete copies (with all attachments and exhibits) of the Notification to the Commission at least thirty (30) days prior to consummating any such transaction (hereafter referred to as the “first waiting period”).

VIII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of a Respondent;
- B. Any proposed acquisition, merger, or consolidation of Respondents; or
- C. Any other change in Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

IX.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent, that Respondent shall, without restraint or interference, permit any duly authorized (i) - /TT2 <</MCID 2Spsen-2(d-2(trat1(t)-i001rS)e1rS)m edize(i)3zedi X.

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Confidential Appendix I

Terumo Purchase Agreement

[Redacted From the Public Record Version, But Incorporated By Reference]

Appendix II
Monitor Agreement

Confidential Appendix II-1

Appendix to Monitor Agreement

[Redacted From the Public Record Version, But Incorporated By Reference]