UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington D.C. 20549

| | washington, D.C. 2004) | |
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| | FORM 8-K | |
| | CURRENT REPORT Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934 | |
| Date o | f Report (Date of earliest event reported): August 2, | 2022 |
| | Axonics, Inc. (Exact name of registrant as specified in its charter) | |
| Delaware ate or other jurisdiction of incorporation) | 001-38721 (Commission File Number) | 45-4744083 (I.R.S. Employer Identification No.) |
| | 26 Technology Drive Irvine, California 92618 (Address of principal executive offices) (Zip Code) | |
| | (949) 396-6322 (Registrant's telephone number, including area code) | |
| | $N\!/\!A$ (Former name or former address, if changed since last report) | |
| propriate box below if the Form ovisions: | 8-K filing is intended to simultaneously satisfy the filing obligation | on of the registrant under any of the |
| Written communications pursua | ant to Rule 425 under the Securities Act (17 CFR 230.425) | |
| Soliciting material pursuant to l | Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) | |
| Dra commoncement communication | otions pursuant to Pula 14d 2(h) under the Evahance Act (17 CED | 240 14d 2(b)) |

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Exchange Act: Title of class **Trading symbol** Name of exchange on which registered Common stock, par value \$0.0001 per share AXNX Nasdaq Global Select Market

Delaware (State or other jurisdiction of incorporation)

Check the appropriate box below if the Form

following provisions:

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. \Box

Item 1.01. Entry into a Material Definitive Agreement.

On August 2, 2022, Axonics, Inc. (the "Company") entered into an underwriting agreement (the "Underwriting Agreement") with BofA Securities, Inc. (the "Underwriter"), relating to an underwritten public offering (the "Offering") of 1,750,000 shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"). The Underwriter agreed to purchase the Common Stock pursuant to the Underwriting Agreement at a price of \$63.85 per share of Common Stock. Under the terms of the Underwriting Agreement, the Company also granted to the Underwriter an option, exercisable in whole or in part at any time for a period of 30 days from the date of the Underwriting Agreement, to purchase up to an additional 262,500 shares of Common Stock from the Company at a price of \$63.85 per share of Common Stock, which option was exercised in full prior to the closing of the Offering. The Offering closed on August 5, 2022.

The Offering was made pursuant to an effective shelf registration statement on Form S-3 (Registration No. 333-238064) and a related prospectus supplement filed with the Securities and Exchange Commission (the "SEC") on August 2, 2022. A copy of the legal opinion of K&L Gates LLP relating to the legality of the issuance and sale of the shares of Common Stock in the Offering is filed herewith as Exhibit 5.1 hereto.

The net proceeds to the Company from the Offering were approximately \$128.3 million, including from the exercise by the Underwriter of its option to purchase additional shares as described above, after deducting estimated offering expenses payable by the Company.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriter, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties and termination provisions. In addition, subject to certain exceptions, the Company and its executive officers and directors have agreed not to sell or otherwise dispose of any of the shares of Common Stock or securities convertible into or exchangeable or exercisable for any shares of Common Stock held by them for a period ending 30 days after the date of the Underwriting Agreement without first obtaining the written consent of the Underwriter.

The foregoing description of the terms of the Underwriting Agreement does not purport to be complete and is subject to, and qualified in its entirety by reference to, the Underwriting Agreement, which is filed herewith as Exhibit 1.1 and is incorporated herein by reference.

The representations, warranties and covenants contained in the Underwriting Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties. Accordingly, the Underwriting Agreement is incorporated herein by reference only to provide investors with information regarding the terms of the Underwriting Agreement, and not to provide investors with any other factual information regarding the Company or its business, and should be read in conjunction with the disclosures in the Company's periodic reports and other filings with the SEC.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements that involve risks and uncertainties. The risks and uncertainties involved include the Company's ability to satisfy certain conditions to closing on a timely basis or at all, market conditions, and other risks detailed from time to time in the Company's periodic reports and other filings with the SEC. You are cautioned not to place undue reliance on forward-looking statements, which are based on the Company's current expectations and assumptions and speak only as of the date of this Current Report on Form 8-K. The Company does not intend to revise or update any forward-looking statement in this Current Report on Form 8-K as a result of new information, future events or otherwise, except as required by law.

Item 8.01. Other Events.

On August 2, 2022, the Company issued press releases announcing that it had launched and priced the Offering, and on August 5, 2022, the Company issued a press release announcing the closing of the Offering. Copies of the press releases are attached as Exhibits 99.1, 99.2 and 99.3, respectively, to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

| | Exhibit No. |
|---------------------|-------------|
| Securities, Inc. | 1.1 |
| | 5.1 |
| | 23.1 |
| | 99.1 |
| | 99.2 |
| | 99.3 |
| line XBRL document. | 104 |
| line XBl | |

SIGNATURES

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

AXONICS, INC.

Dated: August 5, 2022 By: /s/ Raymond W. Cohen

Raymond W. Cohen Chief Executive Officer AXONICS, INC.

(a Delaware corporation)

1,750,000 Shares of Common Stock

UNDERWRITING AGREEMENT

Dated: August 2, 2022

AXONICS, INC.

(a Delaware corporation)

1,750,000 Shares of Common Stock

UNDERWRITING AGREEMENT

August 2, 2022

BofA Securities, Inc. One Bryant Park New York, New York 10036

Ladies and Gentlemen:

Axonics, Inc., a Delaware corporation (the "Company") confirms its agreement with BofA Securities, Inc. (the "Underwriter"), with respect to (i) the sale by the Company and the purchase by the Underwriter of 1,750,000 shares of Common Stock, par value \$0.0001 per share, of the Company ("Common Stock") set forth in Schedule A hereto and (ii) the grant by the Company to the Underwriter of the option described in Section 2(b) hereof to purchase all or any part of 262,500 additional shares of Common Stock. The aforesaid 1,750,000 shares of Common Stock (the "Initial Securities") to be purchased by the Underwriter and all or any part of the 262,500 shares of Common Stock subject to the option described in Section 2(b) hereof (the "Option Securities") are herein called, collectively, the "Securities."

The Company understands that the Underwriter proposes to make a public offering of the Securities as soon as the Underwriter deems advisable after this Agreement has been executed and delivered.

The Company has prepared and filed with the Securities and Exchange Commission (the "Commission") an automatic shelf registration statement on Form S-3 (File No. 333-238064) covering the public offering and sale of certain securities, including the Securities, under the Securities Act of 1933, as amended (the "1933 Act"), and the rules and regulations promulgated thereunder (the "1933 Act Regulations"), which automatic shelf registration statement became effective under Rule 462(e) under the 1933 Act Regulations. Such registration statement, as of any time, means such registration statement as amended by any post-effective amendments thereto to such time, including the exhibits and any schedules thereto at such time, the documents incorporated or deemed to be incorporated by reference therein at such time pursuant to Item 12 of Form S-3 under the 1933 Act and the documents otherwise deemed to be a part thereof as of such time pursuant to Rule 430B under the 1933 Act Regulations ("Rule 430B"), is referred to herein as the "Registration Statement;" provided, however, that the "Registration Statement" without reference to a time means such registration statement as amended by any post-effective amendments thereto as of the time of the first contract of sale for the Securities, which time shall be considered the "new effective date" of such registration statement with respect to the Securities within the meaning of paragraph (f)(2) of Rule 430B, including the exhibits and schedules thereto as of such time, the documents incorporated or deemed incorporated by reference therein at such time pursuant to Item 12 of Form S-3 under the 1933 Act, and the documents otherwise deemed to be a part thereof as of such time pursuant to Rule 430B. Each preliminary prospectus used in connection with the offering of the Securities, including the documents incorporated or deemed to be incorporated by reference therein pursuant to Item 12 of Form S-3 under the 1933 Act, are collectively referred to herein as a "preliminary prospectus." Promptly after execution and delivery of this Agreement, the Company will prepare and file a final prospectus relating to the Securities in accordance with the provisions of Rule 424(b) under the 1933 Act Regulations ("Rule 424(b)"). The

final prospectus, in the form first furnished or made available to the Underwriter for use in connection with the offering of the Securities, including the documents incorporated or deemed to be incorporated by reference therein pursuant to Item 12 of Form S-3 under the 1933 Act, are collectively referred to herein as the "Prospectus." For purposes of this Agreement, all references to the Registration Statement, any preliminary prospectus, the Prospectus or any amendment or supplement to any of the foregoing shall be deemed to include the copy filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval system (or any successor system) ("EDGAR").

As used in this Agreement:

"Applicable Time" means 4:10 P.M., New York City time, on August 2, 2022 or such other time as agreed by the Company and the Underwriter.

"General Disclosure Package" means any Issuer General Use Free Writing Prospectuses issued at or prior to the Applicable Time, the most recent preliminary prospectus (including any documents incorporated therein by reference) that is distributed to investors prior to the Applicable Time and the information included on Schedule C-1 hereto, all considered together.

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the 1933 Act Regulations ("Rule 433"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the 1933 Act Regulations ("Rule 405")) relating to the Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Securities or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"Issuer General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors as evidenced by its being specified in Schedule C-2 hereto.

"Issuer Limited Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the 1933 Act or Rule 163B under the 1933 Act.

"Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the 1933 Act.

All references in this Agreement to financial statements and schedules and other information which is "contained," "included" or "stated" (or other references of like import) in the Registration Statement, any preliminary prospectus or the Prospectus shall be deemed to include all such financial statements and schedules and other information incorporated or deemed incorporated by reference in the Registration Statement, any preliminary prospectus or the Prospectus, as the case may be, prior to the execution and delivery of this Agreement; and all references in this Agreement to amendments or supplements to the Registration Statement, any preliminary prospectus or the Prospectus shall be deemed to include the filing of any document under the Securities Exchange Act of 1934, as amended, and the rules and regulations

promulgated thereunder (collectively, the "1934 Act"), incorporated or deemed to be incorporated by reference in the Registration Statement, such preliminary prospectus or the Prospectus, as the case may be, at or after the execution and delivery of this Agreement.

SECTION 1. Representations and Warranties.

- (a) Representations and Warranties by the Company. The Company represents and warrants to the Underwriter as of the date hereof, the Applicable Time, the Closing Time (as defined below) and any Date of Delivery (as defined below), and agrees with the Underwriter, as follows:
 - (i) <u>Registration Statement and Prospectuses</u>. The Company meets the requirements for use of Form S-3 under the 1933 Act. The Registration Statement is an "automatic shelf registration statement" (as defined in Rule 405) and the Securities have been and remain eligible for registration by the Company on such automatic shelf registration statement. Each of the Registration Statement and any post-effective amendment thereto has become effective under the 1933 Act. No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated. The Company has complied with each request (if any) from the Commission for additional information.

Each of the Registration Statement and any post-effective amendment thereto, at the time of its effectiveness, each deemed effective date with respect to the Underwriter pursuant to Rule 430B(f)(2) under the 1933 Act Regulations, complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations. Each preliminary prospectus, the Prospectus and any amendment or supplement thereto, at the time each was filed with the Commission, and, in each case, at the Applicable Time, the Closing Time and any Date of Delivery complied and will comply in all material respects with the requirements of the 1933 Act and the 1933 Act Regulations and each preliminary prospectus and the Prospectus delivered to the Underwriter for use in connection with this offering was identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

The documents incorporated or deemed to be incorporated by reference in the Registration Statement, any preliminary prospectus and the Prospectus, when they became effective or at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the 1934 Act and the rules and regulations of the Commission under the 1934 Act (the "1934 Act Regulations").

(ii) Accurate Disclosure. Neither the Registration Statement nor any amendment thereto, at its effective time, on the date hereof, at the Closing Time or at any Date of Delivery, contains or will contain an untrue statement of a material fact or omitted or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. At the Applicable Time and any Date of Delivery, none of (A) the General Disclosure Package, (B) any individual Issuer Limited Use Free Writing Prospectus, when considered together with the General Disclosure Package and (C) any individual Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. Neither the Prospectus nor any amendment or

supplement thereto, as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Time or at any Date of Delivery, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The documents incorporated or deemed to be incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus, at the time the Registration Statement became effective or when such documents incorporated by reference were filed with the Commission, as the case may be, when read together with the other information in the Registration Statement, the General Disclosure Package or the Prospectus, as the case may be, did not and will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading.

The representations and warranties in this subsection shall not apply to statements in or omissions from the Registration Statement (or any amendment thereto), the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) made in reliance upon and in conformity with written information furnished to the Company by the Underwriter expressly for use therein. For purposes of this Agreement, the only information so furnished shall be the information in the first paragraph under the heading "Underwriting–Commissions and Discounts," the information in the second and third paragraphs under the heading "Underwriting–Price Stabilization and Short Positions" and the information under the heading "Underwriting–Electronic Distributions" in each case contained in the Prospectus (collectively, the "Underwriter Information").

- (iii) <u>Issuer Free Writing Prospectuses</u>. No Issuer Free Writing Prospectus conflicts or will conflict with the information contained in the Registration Statement or the Prospectus, and any preliminary or other prospectus deemed to be a part thereof that has not been superseded or modified. Any offer that is a written communication relating to the Securities made prior to the initial filing of the Registration Statement by the Company or any person acting on its behalf (within the meaning, for this paragraph only, of Rule 163(c) of the 1933 Act Regulations) has complied with the requirements of Rule 163B under the 1933 Act.
- (iv) <u>Well-Known Seasoned Issuer.</u> (A) At the original effectiveness of the Registration Statement, (B) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the 1933 Act (whether such amendment was by post-effective amendment, incorporated report filed pursuant to Section 13 or 15(d) of the 1934 Act or form of prospectus) and (C) as of the Applicable Time, the Company was and is a "well-known seasoned issuer" (as defined in Rule 405).
- (v) <u>Testing-the-Waters Materials</u>. The Company (A) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Underwriter with entities the Company reasonably believes to be qualified institutional buyers within the meaning of Rule 144A under the 1933 Act or institutions the Company reasonably believes to be accredited investors within the meaning of Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act and otherwise in compliance with the requirements of Section 5(d) of the 1993 Act or Rule 163B under the 1933 Act and (B) has not authorized anyone other than the Underwriter to engage in Testing-the-Waters Communications. The Company reconfirms that the Underwriter has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule C-3 hereto.

(vi) <u>Company Not Ineligible Issuer</u>. At the time of filing the Registration Statement and any post-effective amendment thereto, at the earliest time thereafter that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the 1933 Act Regulations) of the Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

(vii) [Reserved.]

- (viii) <u>Independent Accountants</u>. The accountants who certified the financial statements and supporting schedules included in the Registration Statement, the General Disclosure Package and the Prospectus are independent public accountants as required by the 1933 Act, the 1933 Act Regulations, the 1934 Act, the 1934 Act Regulations and the Public Company Accounting Oversight Board.
- (ix) Financial Statements. The financial statements included or incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus, together with the related schedules and notes, present fairly in all material respects the financial position of the Company and its consolidated subsidiaries at the dates indicated and the statement of operations, stockholders' equity and cash flows of the Company and its consolidated subsidiaries for the periods specified; said financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("GAAP") applied on a consistent basis throughout the periods involved. The supporting schedules, if any, present fairly, in all material respects, in accordance with GAAP the information required to be stated therein. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly, in all material respects, the information shown therein and have been compiled on a basis consistent with that of the audited financial statements included therein. Except as included therein, no historical or pro forma financial statements or supporting schedules are required to be included or incorporated by reference in the Registration Statement, the General Disclosure Package or the Prospectus under the 1933 Act or the 1933 Act Regulations. The interactive data in eXtensible Business Reporting Language incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents the information called for in all material respects and has been prepared in accordance with the Commission's rules and guidelines applicable thereto.
- (x) No Material Adverse Change in Business. Except as otherwise stated therein, since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, (A) there has been no material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business (a "Material Adverse Effect"), (B) there have been no transactions entered into by the Company or any of its subsidiaries, other than those in the ordinary course of business, which are material with respect to the Company and its subsidiaries considered as one enterprise, and (C) there has been no dividend or distribution of any kind declared, paid or made by the Company on any class of its capital stock.
- (xi) Good Standing of the Company. The Company has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and has corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and

to enter into and perform its obligations under this Agreement; and the Company is duly qualified as a foreign corporation to transact business and is in good standing in each other jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure so to qualify or to be in good standing would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

- of Regulation S-X) (each, a "Subsidiaries. Each "significant subsidiary" of the Company (as such term is defined in Rule 1-02 of Regulation S-X) (each, a "Subsidiary" and, collectively, the "Subsidiaries") has been duly organized and is validly existing in good standing under the laws of the jurisdiction of its incorporation or organization, has corporate or similar power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus and is duly qualified to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to so qualify or to be in good standing would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Except as otherwise disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, all of the issued and outstanding capital stock of each Subsidiary has been duly authorized and validly issued, is fully paid and non-assessable and is owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance, claim or equity. None of the outstanding shares of capital stock of any Subsidiary were issued in violation of the preemptive or similar rights of any securityholder of such Subsidiary. The only subsidiaries of the Company are the subsidiaries listed on Exhibit 21.1 to the Company's Annual Report on Form 10-K, filed with the Commission on March 1, 2022.
- (xiii) <u>Capitalization</u>. The Company is authorized to issue 10,000,000 shares of preferred stock, par value \$0.0001 per share ("Preferred Stock") and 75,000,000 shares of Common Stock. As of July 28, 2022, no shares of Preferred Stock were issued and outstanding and 47,111,116 shares of Common Stock were issued and outstanding. The outstanding shares of capital stock of the Company have been duly authorized and validly issued and are fully paid and non-assessable. None of the outstanding shares of capital stock of the Company were issued in violation of the preemptive or other similar rights of any securityholder of the Company.
 - (xiv) <u>Authorization of Agreement</u>. This Agreement has been duly authorized, executed and delivered by the Company.
- Authorization and Description of Securities. The Securities to be purchased by the Underwriter from the Company have been duly authorized for issuance and sale to the Underwriter pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued and fully paid and non-assessable; and the issuance of the Securities is not subject to the preemptive or other similar rights of any securityholder of the Company. The Common Stock conforms, in all material respects, to all statements relating thereto contained in the Registration Statement, the General Disclosure Package and the Prospectus and such description conforms, in all material respects, to the rights set forth in the instruments defining the same. No holder of Securities will be subject to personal liability solely by reason of being such a holder.
- (xvi) <u>Registration Rights</u>. There are no persons with registration rights or other similar rights to have any securities registered for sale pursuant to the Registration Statement or otherwise registered for sale or sold by the Company under the 1933 Act pursuant to this Agreement, other

than those rights that have been disclosed in the Registration Statement, the General Disclosure Package and the Prospectus and have been waived or have lapsed in accordance with their terms.

- (xvii) Absence of Violations, Defaults and Conflicts. Neither the Company nor any of its subsidiaries is (A) in violation of its charter, by-laws or similar organizational document, (B) in default in the performance or observance of any obligation, agreement, covenant or condition contained in any contract, indenture, mortgage, deed of trust, loan or credit agreement, note, lease or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound or to which any of the properties or assets of the Company or any subsidiary is subject (collectively, "Agreements and Instruments"), except for such defaults that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or (C) in violation of any law, statute, rule, regulation, judgment, order, writ or decree of any arbitrator, court, governmental body, regulatory body, administrative agency or other authority, body or agency having jurisdiction over the Company or any of its subsidiaries or any of their respective properties, assets or operations (each, a "Governmental Entity"), except for such violations that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The execution, delivery and performance of this Agreement and the consummation of the transactions contemplated herein and in the Registration Statement, the General Disclosure Package and the Prospectus (including the issuance and sale of the Securities and the use of the proceeds from the sale of the Securities as described therein under the caption "Use of Proceeds") and compliance by the Company with its obligations hereunder have been duly authorized by all necessary corporate action and do not and will not, whether with or without the giving of notice or passage of time or both, conflict with or constitute a breach of, or default or Repayment Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or any subsidiary pursuant to the Agreements and Instruments (except for such conflicts, breaches, defaults or Repayment Events or liens, charges or encumbrances that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect), nor will such action result in any violation of (x) the provisions of the charter, by-laws or similar organizational document of the Company or any of its subsidiaries or (y) any law, statute, rule, regulation, judgment, order, writ or decree of any Governmental Entity, except, in the case of clause (y), for such violations as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. As used herein, a "Repayment Event" means any event or condition which gives the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.
- (xviii) <u>Absence of Labor Dispute</u>. No labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is imminent, and the Company is not aware of any existing or imminent labor disturbance by the employees of any of its or any subsidiary's principal suppliers, manufacturers, customers or contractors, which, in either case, would, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.
- (xix) Absence of Proceedings. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, there is no action, suit, proceeding, inquiry or investigation before or brought by any Governmental Entity (including, without limitation, the U.S. Food and Drug Administration (the "FDA") or the European Medicines Agency (the "EMA")) now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, or which would reasonably be expected to materially and adversely affect their respective properties or assets or the consummation of the transactions contemplated in this

Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental actions, suits, inquiries, investigations or proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject which are not described in the Registration Statement, the General Disclosure Package and the Prospectus, including ordinary routine litigation incidental to the business, would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

- (xx) <u>Accuracy of Exhibits</u>. There are no contracts or documents which are required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as exhibits to the Registration Statement which have not been so described and filed as required.
- (xxi) Absence of Further Requirements. No filing with, or authorization, approval, consent, license, order, registration, qualification or decree of, any Governmental Entity is necessary or required for the performance by the Company of its obligations hereunder, in connection with the offering, issuance or sale of the Securities hereunder or the consummation of the transactions contemplated by this Agreement, except such as have been already obtained or as may be required under the 1933 Act, the 1933 Act Regulations, the rules of the Nasdaq Global Select Market, state securities laws or the rules of FINRA.
- (xxii) <u>Possession of Licenses and Permits</u>. The Company and its subsidiaries possess, or qualify for an exemption from any applicable requirement to obtain, such permits, licenses, approvals, consents and other authorizations (collectively, "Governmental Licenses") issued by the appropriate Governmental Entities necessary to conduct the business now operated by them (including, without limitation, all such permits, licenses, approvals, consents and other authorizations required by the FDA, the EMA, or any other federal, state, local or foreign agencies or bodies engaged in the regulation of clinical trials, medical devices or activities related to the business now operated by the Company and its subsidiaries in such jurisdictions), except where the failure so to possess or qualify would not, singly or in the aggregate, be reasonably expected to result in a Material Adverse Effect. The Company and its subsidiaries are in compliance with the terms and conditions of all Governmental Licenses, except where the failure so to comply would not, singly or in the aggregate, be reasonably expected to result in a Material Adverse Effect. All of the Governmental Licenses are valid and in full force and effect, except where the invalidity of such Governmental Licenses or the failure of such Governmental Licenses to be in full force and effect would not, singly or in the aggregate, be reasonably expected to result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of any Governmental Licenses which, singly or in the aggregate, if the subject of an unfavorable decision, ruling or finding, would be reasonably expected to result in a Material Adverse Effect. The Company and its subsidiaries (i) are, and at all times have been, in compliance with all statutes, rules and regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, storage, import, export or disposal of any product manufactured or distributed by them ("Applicable Laws"), except where such noncompliance would not, singly or in the aggregate, be reasonably expected to result in a Material Adverse Effect; and (ii) have not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from any court or arbitrator or governmental or regulatory authority alleging or asserting noncompliance with (x) any Applicable Laws or (y) any Governmental Licenses required by any such Applicable Laws, except where being in contravention of any of the foregoing representations or warranties, singly or in the aggregate, would not be reasonably expected to result in a Material Adverse Effect.

(xxiii) <u>Title to Property</u>. Neither the Company nor any of its subsidiaries own any real property. All of the leases and subleases material to the business of the Company and its subsidiaries, considered as one enterprise, and under which the Company or any of its subsidiaries holds properties described in the Registration Statement, the General Disclosure Package or the Prospectus, are in full force and effect, and neither the Company nor any such subsidiary has any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company or any subsidiary under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company or such subsidiary to the continued possession of the leased or subleased premises under any such lease or sublease.

(xxiv) Possession of Intellectual Property. The Company and its subsidiaries own or possess, have license to, or can acquire, all patents, patent rights, statutory invention rights, community designs, invention disclosures, rights in utility models and industrial designs, inventions, registered and unregistered copyrights (including copyrights in software), intellectual property rights in technology and software, data, know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures), trademarks, service marks, business names, trade names, logos, slogans, trade dress, design rights, Internet domain names, social media accounts, any other designations of source or origin, and any applications (including provisional applications), registrations, or renewals for any of the foregoing, rights to publicity and privacy and/or other intellectual property (collectively, "Intellectual Property") necessary in all material respects to carry on the business now operated by them and as currently proposed to be conducted as described in the Registration Statement, the General Disclosure Package and the Prospectus. (A) Neither the Company nor any of its subsidiaries has received any written notice of nor has engaged in any infringement, misappropriation, violation of or conflict with any Intellectual Property of others, (B) there is no pending or threatened action, suit, proceeding or claim against the Company or any of its subsidiaries regarding the subject matter of the foregoing and (C) the Company and its subsidiaries are unaware of any facts which would form a reasonable basis for any such claim. (1) All Intellectual Property owned by or exclusively licensed to the Company or any of its subsidiaries (such Intellectual Property, the "Company Intellectual Property") is valid and enforceable in all material respects, (2) there is no pending or threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Company Intellectual Property and (3) the Company is unaware of any facts which would form a reasonable basis for any such claim. The Company is not aware of any infringement, misappropriation, conflict or violation of any Company Intellectual Property by third parties and there is no pending action, suit or proceeding by the Company or any of its subsidiaries against a third party with respect to any such infringement, misappropriation, conflict or violation. (I) The Company and its subsidiaries have complied in all material respects with the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, (II) neither the Company nor any of its subsidiaries has received any written notice alleging any such noncompliance, and (III) all such agreements are in full force and effect. All Company Intellectual Property has been duly maintained and is in full force and effect, and there are no material defects in any of the Company Intellectual Property. Each person who is or was an employee or contractor of the Company or any of its subsidiaries and who is, was or, in the case of current employees and contractors, is reasonably expected to be involved in the creation or development of any Intellectual Property for or on behalf of the Company has executed an agreement containing an assignment to the Company or any of its subsidiaries of such person's rights in and to such Intellectual Property. The Company is not aware of any material violation by any current or former employee of the Company or any of its subsidiaries of any term of any agreement or covenant to or with a former employer of such employee where the basis of such violation relates to such employee's employment with the Company or any of its subsidiaries or actions undertaken by the employee while employed with

the Company or any of its subsidiaries. The Company has taken all reasonable steps necessary to maintain the confidentiality of the material trade secrets and other material confidential Intellectual Property used in connection with the business of the Company and its subsidiaries, and the confidentiality of such material trade secrets and material confidential Intellectual Property has not been compromised in such a matter would deprive the Company's material trade secrets from the protections afforded to trade secrets under the applicable law, or which would preclude the Company from enforcing confidentiality obligations against persons who have agreed, or otherwise have a duty to, maintain the confidentiality of such material confidential Intellectual Property.

(xxv) Environmental Laws. Except as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, (A) neither the Company nor any of its subsidiaries is in violation of any applicable federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mold (collectively, "Hazardous Materials") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "Environmental Laws"), (B) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements, (C) there are no pending or, to the knowledge of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigations or proceedings relating to any Environmental Law against the Company or any of its subsidiaries and (D) to the knowledge of the Company, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or Governmental Entity, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(xxvi) Accounting Controls and Disclosure Controls. The Company and each of its subsidiaries maintain effective internal control over financial reporting (as defined under Rules 13a-15 and 15d-15 of the 1934 Act Regulations) and a system of internal accounting controls sufficient to provide reasonable assurances that (A) transactions are executed in accordance with management's general or specific authorization; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain accountability for assets; (C) access to assets is permitted only in accordance with management's general or specific authorization; (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences; and (E) the interactive data in eXtensible Business Reporting Language incorporated by reference in the Registration Statement, the General Disclosure Package and the Prospectus fairly presents the information called for in all material respects and is prepared in accordance with the Commission's rules and guidelines applicable thereto. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year, there has been (1) no material weakness in the Company's internal control over financial reporting (whether or not remediated) and (2) no change in the Company's internal control over financial reporting that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting. The Company maintains an effective system of disclosure controls and procedures (as defined in Rule 13a-15 and Rule 15d-15 under the 1934 Act Regulations) that are designed to ensure that

information required to be disclosed by the Company in the reports that it files or submits under the 1934 Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms, and is accumulated and communicated to the Company's management, including its principal executive officer or officers and principal financial officer or officers, as appropriate, to allow timely decisions regarding disclosure.

(xxvii) <u>Compliance with the Sarbanes-Oxley Act.</u> There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply in all material respects with any provision of the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated in connection therewith (the "Sarbanes-Oxley Act") with which the Company is required to comply, including Section 402 related to loans and Sections 302 and 906 related to certifications.

(xxviii) Payment of Taxes. All United States federal income tax returns of the Company and its subsidiaries required by law to be filed as of the date hereof have been filed and all taxes shown by such returns or otherwise assessed, which are due and payable, have been paid, except assessments against which appeals have been or will be promptly taken and as to which adequate reserves have been provided in accordance with GAAP by the Company. The Company and its subsidiaries have filed all other tax returns that are required to have been filed by them pursuant to applicable foreign, state, local or other law except insofar as the failure to file such returns would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and have paid all taxes due pursuant to such returns or pursuant to any assessment received by the Company and its subsidiaries, except for such taxes, if any, as are being contested in good faith and as to which adequate reserves have been established by the Company in accordance with GAAP, and except insofar as the failure to pay such taxes would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. The charges, accruals and reserves on the books of the Company in respect of any income and corporation tax liability for any years not finally determined are adequate to meet any assessments or re-assessments for additional income tax for any years not finally determined, except to the extent of any inadequacy that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

(xxix) <u>Insurance</u>. The Company and its subsidiaries carry or are entitled to the benefits of insurance, with financially sound and reputable insurers, in such amounts and covering such risks as is generally maintained by companies of established repute and comparable size engaged in the same or similar business, and all such insurance is in full force and effect. The Company has no reason to believe that it or any of its subsidiaries will not be able (A) to renew its existing insurance coverage as and when such policies expire or (B) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither of the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(xxx) <u>Investment Company Act</u>. The Company is not required, and upon the issuance and sale of the Securities as herein contemplated and the application of the net proceeds therefrom as described in the Registration Statement, the General Disclosure Package and the Prospectus will not be required, to register as an "investment company" under the Investment Company Act of 1940, as amended (the "1940 Act").

(xxxi) Absence of Manipulation. Neither the Company nor, to the knowledge of the Company, any affiliate of the Company has taken, nor will the Company or any affiliate take, directly or indirectly, any action which is designed, or would reasonably be expected, to cause or

result in, or which constitutes, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Securities or to result in a violation of Regulation M under the 1934 Act.

(xxxii) Foreign Corrupt Practices Act. None of the Company or any of its subsidiaries or any director or officer thereof nor, to the knowledge of the Company, any agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries is aware of, or has taken, any action, directly or indirectly, that would result in a violation by such persons of the Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (the "FCPA"), including, without limitation, making use of the mails or any means or instrumentality of interstate commerce corruptly in furtherance of an offer, payment, promise to pay or authorization of the payment of any money, or other property, gift, promise to give, or authorization of the giving of anything of value to any "foreign official" (as such term is defined in the FCPA) or any foreign political party or official thereof or any candidate for foreign political office, in contravention of the FCPA and the Company, its subsidiaries and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted and maintained and will continue to maintain policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith. Neither the Company nor its subsidiaries will use, directly or indirectly, the proceeds of the offering in furtherance of an offer, payment, promise to pay, or authorization of the payment or giving of money, or anything else of value, to any person in violation of any applicable anti-corruption laws.

(xxxiii) <u>Money Laundering Laws</u>. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "Money Laundering Laws"); and no action, suit or proceeding by or before any Governmental Entity involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(xxxiv) OFAC. None of the Company or any of its subsidiaries or any director or officer thereof, nor to the knowledge of the Company, any agent, employee, affiliate or representative of the Company or any of its subsidiaries is a Person, or is owned or controlled by one or more Persons, currently the subject or target of any sanctions administered or enforced by the United States Government, including, without limitation, the U.S. Department of the Treasury's Office of Foreign Assets Control ("OFAC"), the United Nations Security Council, the European Union, Her Majesty's Treasury, or other relevant sanctions authority (collectively, "Sanctions"), nor located, organized or resident in a country or territory that is the subject of Sanctions (including, without limitation, the so-called Donetsk People's Republic, the so-called Luhansk People's Republic, Crimea region of Ukraine, Cuba, Iran, North Korea and Syria); and the Company will not directly or indirectly use the proceeds of the sale of the Securities, or lend, contribute or otherwise make available such proceeds to any subsidiaries, joint venture partners or other Person, to fund or facilitate any activities of or business with any Person, or in any country or territory, that, at the time of such funding or facilitation, is the subject of Sanctions or in any other manner that will result in a violation by any Person (including any Person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in, and are not now knowingly engaged in, any dealings or transactions with any Person, or in any country or territory, that at the time of the dealing or transaction is or was the subject of Sanctions.

(xxxv) <u>Lending Relationship</u>. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Company (i) does not have any material lending or other relationship with any bank or lending affiliate of the Underwriter and (ii) does not intend to use any of the proceeds from the sale of the Securities to repay any outstanding debt owed to any affiliate of the Underwriter.

(xxxvi) <u>Statistical and Market-Related Data</u>. Any statistical and market-related data included in the Registration Statement, the General Disclosure Package or the Prospectus are based on or derived from sources that the Company believes, after reasonable inquiry, to be reliable and accurate. To the Company's knowledge, after reasonable investigation, it does not require the consent of any third party for the use of any such data except as has already been obtained.

(xxxvii)No Rated Securities. Neither the Company nor its subsidiaries have any debt securities or preferred stock that are rated by any "nationally recognized statistical rating agency" (as defined in Section 3(a)(62) of the 1934 Act).

ERISA Compliance. Except as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, the Company and its subsidiaries and any "Employee Benefit Plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations promulgated thereunder (collectively, "ERISA")) for which the Company, its subsidiaries or their "ERISA Affiliates" (as defined below) would have any liability (each, a "Plan") are in compliance in all respects with ERISA and each Plan has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to, ERISA and the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code"). "ERISA Affiliate" means, with respect to the Company, any member of any group of organizations described in Sections 414(b), (c), (m) or (o) of the Code of which the Company or such subsidiary is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any Plan that is a "Pension Plan" (within the meaning of Section 3(2) of ERISA) (each, a "Pension Plan"). No Pension Plan, if such Pension Plan were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA), as the fair market value of the assets under each Plan (excluding for these purposes accrued but unpaid contributions) exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur, with respect to a Pension Plan, any obligation or liability under (A) Title IV of ERISA with respect to termination of, or withdrawal from, any Plan, (B) Sections 412 and 430, 4971, 4975 or 4980B of the Code or (C) Sections 302 and 303, 406, 4063 and 4064 of ERISA. Each Plan that is intended to be qualified under Section 401(a) of the Code is so qualified and nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification. There is no pending audit or investigation by the Internal Revenue Service, the U.S. Department of Labor, the Pension Benefit Guaranty Corporation or any other governmental or foreign regulatory entity or agency with respect to any Plan that could reasonably be expected to result in liability to the Company or any of its subsidiaries. Neither the Company nor any of its subsidiaries have any "accumulated post-retirement benefit obligations" (within the meaning of Statement of Financial Accounting Standards 106).

(xxxix) <u>Research Studies and Trials</u>. The research studies and trials conducted by or on behalf of, or sponsored by, the Company and its subsidiaries, or in which the Company and its subsidiaries have participated, that are described in the Registration Statement, the General Disclosure Package or the Prospectus, or the results of which are referred to in the Registration

Statement, the General Disclosure Package or the Prospectus, as applicable, were and, if still pending, are being, conducted in all material respects in accordance with applicable experimental protocols, procedures and controls pursuant to, where applicable, accepted professional and scientific standards for products or product candidates comparable to those being developed by the Company, its subsidiaries and all applicable statutes, rules and regulations of the FDA, the EMA and other comparable medical device regulatory agencies to which they are subject; the descriptions of the results of such studies and trials contained in the Registration Statement, the General Disclosure Package or the Prospectus do not contain any misstatement of a material fact or omit to state a material fact necessary to make such statements not misleading; there are no research studies or trials not described in the Disclosure Package and the Prospectus the results of which reasonably call into question in any material respect the results of the research studies and trials described in the Registration Statement, the General Disclosure Package or Prospectus; and neither the Company nor its subsidiaries have received any written notices or correspondence from the FDA, the EMA or any other foreign, state or local governmental body exercising comparable authority or any institutional review board or comparable authority requiring or threatening the premature termination, suspension, material modification or clinical hold of any research studies or trials conducted by or on behalf of, or sponsored by, the Company and its subsidiaries or in which the Company and its subsidiaries have participated that are described in the Registration Statement, the General Disclosure Package or the Prospectus, and, to the Company's knowledge, there are no reasonable grounds for the same. There has not been any violation of applicable law or regulation by the Company or its subsidiaries in their product development, submissions or reports to any regulatory authority that could reasonably be expected to require investigation, corrective action or enforcement action, except where such violation would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

- (xl) Health Care Authorizations. The Company and its subsidiaries have submitted and possesses, or qualify for applicable exemptions to, such valid and current registrations, listings, approvals, clearances, licenses, certificates, authorizations or permits and supplements or amendments thereto (collectively, "Health Care Authorizations") issued or required by the appropriate state, federal or foreign regulatory agencies or bodies necessary to conduct their business as described in the Registration Statement, the General Disclosure Package and the Prospectus, including, without limitation, all such Health Care Authorizations required by the FDA, the EMA, the Department of Health and Human Services or any other state, federal or foreign agencies or bodies engaged in the regulation of medical devices, except as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. Neither the Company nor any of its subsidiaries has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such Health Care Authorization, except where such revocation, modification or non-compliance would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.
- (xli) Compliance with Health Care Laws. The Company and its subsidiaries are, and have been, in compliance with all applicable Health Care Laws, and have not engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program, except where such noncompliance, false claims liability or civil penalties would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect. For purposes of this Agreement, "Health Care Laws" means all health care laws applicable to the Company and its subsidiaries, including, but not limited to: the Federal Food, Drug, and Cosmetic Act, the Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. §

1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and other similar laws in foreign jurisdictions, and any and all other applicable state and local health care laws and the regulations promulgated pursuant to such laws, each as amended from time to time. Neither the Company nor any of its subsidiaries have received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. Neither the Company nor any of its subsidiaries is a party to or has ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, any of its subsidiaries nor, to the Company's knowledge, any of their employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal or foreign health care program or human research study or trial or, to the knowledge of the Company is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(xlii) Health Care Products Manufacturing. The manufacture of the Company's and its subsidiaries' products by or on behalf of the Company and its subsidiaries is being conducted in compliance in all material respects with all applicable Health Care Laws, including, without limitation, the FDA's current good manufacturing practice regulations at 21 CFR Part 820, and, to the extent applicable, the respective counterparts thereof promulgated by governmental authorities in countries outside the United States. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, neither the Company nor any of its subsidiaries has had any manufacturing site (whether Company-owned, subsidiary-owned or that of a third party manufacturer for the Company's or its subsidiaries' products) subject to a governmental authority (including FDA) shutdown or import or export prohibition, nor received any FDA or other governmental authority "warning letters," or "untitled letters" alleging or asserting material noncompliance with any applicable Health Care Laws, requests to make material changes to the Company's or its subsidiaries' products, processes or operations, or similar correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable Health Care Laws, other than those that have been satisfactorily addressed and/or closed with the FDA or other governmental authority. To the knowledge of the Company, neither the FDA nor any other governmental authority is considering such action.

(xliii) No Safety Notices. (A) There have been no recalls, field notifications, field corrections, market withdrawals or replacements, warnings, "dear doctor" letters, investigator notices, safety alerts or other notice of action relating to an alleged lack of safety, efficacy, or regulatory compliance of the Company's or its subsidiaries' products ("Safety Notices"), except as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and (B) to the knowledge of the Company, there are no facts that would be reasonably likely to result in (1) a Safety Notice with respect to the Company's or its subsidiaries' products, (2) a material change in labeling of any of the Company's or its subsidiaries' products, or (3) a termination or suspension of marketing or testing of any of the Company's or its subsidiaries'

products, except, in each of cases (1), (2) or (3) such as would not, singly or in the aggregate, reasonably be expected to result in a Material Adverse Effect.

- (xliv) Privacy and Data Protection. The Company and each of its subsidiaries have complied, and are presently in compliance, with its privacy and security policies and with all obligations under applicable laws and regulations regarding the collection, use, transfer, storage, protection, disposal or disclosure of personally identifiable information or any other information collected from or provided by third parties. The Company and its subsidiaries have taken commercially reasonable steps to protect the information technology assets and data used in connection with the operation of the business of the Company or its subsidiaries, including the confidentiality of such data. The Company and its subsidiaries have established commercially reasonable disaster recovery and security plans, procedures and facilities for the business of the Company and its subsidiaries, including, without limitation, for the information technology assets and data held or used by or for the Company or any of its subsidiaries. There has been no material security breach or attack or other compromise (including any unauthorized or illegal use or access) of or relating to any such information technology asset or data, and to the knowledge of the Company, the Company and its subsidiaries are not the subject to any inquiry or investigation by any Governmental Entity regarding any of the foregoing. Such information technology assets are adequate and operational for, in accordance with their documentation and functional specifications, the business of the Company and its subsidiaries as now operated and as currently proposed to be conducted as described in the Registration Statement, the General Disclosure Package and the Prospectus.
- (b) Officer's Certificates. Any certificate signed by any officer of the Company or any of its subsidiaries delivered to the Underwriter or to counsel for the Underwriter shall be deemed a representation and warranty by the Company to the Underwriter as to the matters covered thereby.

SECTION 2. Sale and Delivery to Underwriter; Closing.

- (a) *Initial Securities*. On the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company agrees to sell to the Underwriter and the Underwriter agrees to purchase from the Company, at the price per share set forth in Schedule A, that number of Initial Securities set forth in Schedule A opposite the name of the Underwriter.
- (b) Option Securities. In addition, on the basis of the representations and warranties herein contained and subject to the terms and conditions herein set forth, the Company hereby grants an option to the Underwriter to purchase up to an additional 262,500 shares of Common Stock, at the price per share set forth in Schedule A, less an amount per share equal to any dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities. The option hereby granted may be exercised for 30 days after the date hereof and may be exercised in whole or in part at any time from time to time upon notice by the Underwriter to the Company setting forth the number of Option Securities as to which the Underwriter is then exercising the option and the time and date of payment and delivery for such Option Securities. Any such time and date of delivery (a "Date of Delivery") shall be determined by the Underwriter, but shall not be later than seven full business days after the exercise of said option, nor in any event prior to the Closing Time.
- (c) Payment. Payment of the purchase price for, and delivery of certificates or security entitlements for, the Initial Securities shall be made at the offices of Shearman & Sterling LLP, 599 Lexington Avenue, New York, New York 10022, or at such other place as shall be agreed upon by the Underwriter and the Company, at 9:00 A.M. (New York City time) on August 5, 2022, or such other time

not later than ten business days after such date as shall be agreed upon by the Underwriter and the Company (such time and date of payment and delivery being herein called "Closing Time").

In addition, in the event that any or all of the Option Securities are purchased by the Underwriter, payment of the purchase price for, and delivery of certificates or security entitlements for, such Option Securities shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Underwriter and the Company, on each Date of Delivery as specified in the notice from the Underwriter to the Company.

Payment shall be made to the Company by wire transfer of immediately available funds to a bank account designated by the Company against delivery to the Underwriter for the account of the Underwriter of certificates or security entitlements for the Securities to be purchased by it.

SECTION 3. Covenants of the Company. The Company covenants with the Underwriter as follows:

- Compliance with Securities Regulations and Commission Requests. The Company, subject to Section 3(b), will comply with the requirements of Rule 430B, and will promptly notify the Underwriter, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed, (ii) of the receipt of any comments from the Commission, (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus including any document incorporated by reference therein or for additional information, (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any posteffective amendment or of any order preventing or suspending the use of any preliminary prospectus or the Prospectus, or of the suspension of the qualification of the Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the 1933 Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the 1933 Act in connection with the offering of the Securities. The Company will effect all filings required under Rule 424(b), in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and will take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company will use its reasonable best efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof as soon as practicable. The Company shall pay the required Commission filing fees relating to the Securities within the time required by Rule 456(b)(1)(i) under the 1933 Act Regulations without regard to the proviso therein and otherwise in accordance with Rules 456(b) and 457(r) under the 1933 Act Regulations (including, if applicable, by updating the "Calculation of Filing Fees Table" exhibit in accordance with Rule 456(b)(1)(ii) either in a post-effective amendment filed at the time of the fee payment or in the manner specified by Rule 424(g) in a prospectus filed pursuant to Rule 424(b)).
- (b) Continued Compliance with Securities Laws. The Company will comply with the 1933 Act and the 1933 Act Regulations, the 1934 Act and the 1934 Act Regulations so as to permit the completion of the distribution of the Securities as contemplated in this Agreement and in the Registration Statement, the General Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172 of the 1933 Act Regulations ("Rule 172"), would be) required by the 1933 Act to be delivered in connection with sales of the Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriter or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, (ii) amend or supplement the

General Disclosure Package or the Prospectus in order that the General Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the General Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the 1933 Act or the 1933 Act Regulations, the Company will promptly (A) give the Underwriter notice of such event, (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the General Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Underwriter with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Underwriter or counsel for the Underwriter may reasonably request. The Company will give the Underwriter notice of its intention to make any filing pursuant to the 1934 Act and the 1934 Act Regulations from the Applicable Time to the Closing Time and will furnish the Underwriter with copies of any such documents a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Underwriter or counsel for the Underwriter shall reasonably object.

- (c) Delivery of Registration Statements. The Company has furnished or will deliver to the Underwriter and counsel for the Underwriter, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriter, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits). The copies of the Registration Statement and each amendment thereto furnished to the Underwriter will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.
- (d) Delivery of Prospectuses. The Company has delivered to the Underwriter, without charge, as many copies of each preliminary prospectus as the Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the 1933 Act. The Company will furnish to the Underwriter, without charge, during the period when a prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, such number of copies of the Prospectus (as amended or supplemented) as the Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriter will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.
- (e) Blue Sky Qualifications. The Company will use its reasonable best efforts, in cooperation with the Underwriter, to qualify the Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Underwriter may designate and to maintain such qualifications in effect so long as required to complete the distribution of the Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.
- (f) Rule 158. The Company will timely file such reports pursuant to the 1934 Act as are necessary in order to make generally available to its securityholders as soon as practicable an earnings

statement for the purposes of, and to provide to the Underwriter the benefits contemplated by, the last paragraph of Section 11(a) of the 1933 Act.

- (g) Use of Proceeds. The Company will use the net proceeds received by it from the sale of the Securities in the manner specified in the Registration Statement, the General Disclosure Package and the Prospectus under "Use of Proceeds."
- (h) Listing. The Company will use its reasonable best efforts to effect and maintain the listing of the Common Stock (including the Securities) on the Nasdaq Global Select Market.
- Restriction on Sale of Securities. During a period of 30 days from the date of the Prospectus, the Company will not, without the prior written consent of the Underwriter. (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or file any registration statement or make a confidential submission under the 1933 Act with respect to any of the foregoing or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Common Stock, whether any such swap or transaction described in clause (i) or (ii) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise. The foregoing sentence shall not apply to (A) the Securities to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (D) any shares of Common Stock issued pursuant to any non-employee director stock plan or dividend reinvestment plan referred to in the Registration Statement, the General Disclosure Package and the Prospectus, (E) the filing of a registration statement on Form S-8 or any successor form thereto with respect to the registration of securities to be offered under any employee benefit or equity incentive plans of the Company referred to in the Registration Statement, the General Disclosure Package and the Prospectus, or (F) the issuance of shares of Common Stock, restricted stock awards or securities convertible into or exercisable or exchangeable for shares of Common Stock in connection with commercial relationships or other strategic transactions, provided that the aggregate number of shares of Common Stock, restricted stock awards and shares of Common Stock issuable upon the conversion, exercise or exchange of securities (on an as converted or as exercised basis, as the case may be) issued pursuant to this clause (F) shall not exceed 2% of the total number of shares of Common Stock issued and outstanding immediately following the issuance and sale of the Securities at the Closing Time pursuant hereto.
- (j) Reporting Requirements. The Company, during the period when a Prospectus relating to the Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the 1933 Act, will file all documents required to be filed with the Commission pursuant to the 1934 Act within the time periods required by the 1934 Act and 1934 Act Regulations.
- (k) Issuer Free Writing Prospectuses. The Company agrees that, unless it obtains the prior written consent of the Underwriter, it will not make any offer relating to the Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Underwriter will be deemed to have consented to the Issuer Free Writing Prospectuses listed on Schedule C-2 hereto and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Underwriter. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented

to, by the Underwriter as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, any preliminary prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriter and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(l) Testing-the-Waters Materials. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriter and will promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

SECTION 4. Payment of Expenses.

Expenses. The Company will pay or cause to be paid all expenses incident to the performance of its obligations under this Agreement, including (i) the preparation, printing and filing of the Registration Statement (including financial statements and exhibits) as originally filed and each amendment thereto, (ii) the preparation, printing and delivery to the Underwriter of copies of each preliminary prospectus, each Issuer Free Writing Prospectus and the Prospectus and any amendments or supplements thereto and any costs associated with electronic delivery of any of the foregoing by the Underwriter to investors, (iii) the preparation, issuance and delivery of the certificates or security entitlements for the Securities to the Underwriter, including any stock or other transfer taxes and any stamp or other duties payable upon the sale, issuance or delivery of the Securities to the Underwriter, (iv) the fees and disbursements of the Company's counsel, accountants and other advisors, (v) subject to the limitation set forth in clause (viii) below, the qualification of the Securities under securities laws in accordance with the provisions of Section 3(e) hereof, including filing fees and the reasonable fees and disbursements of counsel for the Underwriter in connection therewith and in connection with the preparation of the Blue Sky Survey and any supplement thereto, (vi) the fees and expenses of any transfer agent or registrar for the Securities, (vii) the costs and expenses of the Company relating to investor presentations on any "road show" undertaken in connection with the marketing of the Securities, including without limitation, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged by the Company in connection with the road show presentations, travel and lodging expenses of the representatives and officers of the Company and any such consultants (it being understood that the Underwriter will pay or cause to be paid the travel and lodging expenses of its representatives), and 50% of the cost of any aircraft and other transportation chartered in connection with the road show, with the remaining 50% of the cost of such aircraft being paid by the Underwriter, provided that the Company and the Underwriter agree in advance to the charter of any aircraft, (viii) the filing fees incident to, and the reasonable fees and disbursements of counsel to the Underwriter in connection with, the review by FINRA of the terms of the sale of the Securities; provided that the amount payable by the Company pursuant to this clause (viii) when taken together with amounts payable pursuant to clause (v) shall not exceed \$20,000 in the aggregate, (ix) the fees and expenses incurred in connection with the listing of the Securities on the Nasdaq Global Select Market and (x) the costs and expenses (including, without limitation, any damages

or other amounts payable in connection with legal or contractual liability) associated with the reforming of any contracts for sale of the Securities made by the Underwriter caused by a breach of the representation contained in the third sentence of Section 1(a)(ii).

- (a) Termination of Agreement. If this Agreement is terminated by the Underwriter in accordance with the provisions of Section 5 or Section 9(a)(i) hereof, the Company shall reimburse the Underwriter for all of its reasonable and documented out-of-pocket expenses, including the reasonable and documented fees and disbursements of counsel for the Underwriter.
- SECTION 5. <u>Conditions of Underwriter's Obligations</u>. The obligations of the Underwriter hereunder are subject to the accuracy of the representations and warranties of the Company contained herein or in certificates of any officer of the Company delivered pursuant to the provisions hereof, to the performance by the Company of its covenants and other obligations hereunder, and to the following further conditions:
- (a) Effectiveness of Registration Statement. The Registration Statement has become effective and, at the Closing Time, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the 1933 Act, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated; and the Company has complied with each request (if any) from the Commission for additional information. The Company shall have paid the required Commission filing fees relating to the Securities within the time period required by Rule 456(b)(1)(i) under the 1933 Act Regulations without regard to the proviso therein and otherwise in accordance with Rules 456(b) and 457(r) under the 1933 Act Regulations and, if applicable, shall have updated the "Calculation of Filing Fees Table" exhibit in accordance with Rule 456(b)(1)(ii) either in a post-effective amendment filed at the time of payment or in the manner specified by Rule 424(g) in a prospectus filed pursuant to Rule 424(b).
 - (b) Opinions of Counsel for Company. At the Closing Time, the Underwriter shall have received:
 - (i) the opinion and negative assurance letter, dated the Closing Time, of K&L Gates LLP, counsel for the Company, in form and substance reasonably satisfactory to counsel for the Underwriter; and
 - (ii) the opinion, dated the Closing Time, of Kilpatrick Townsend & Stockton LLP, intellectual property counsel for the Company, in form and substance satisfactory to counsel for the Underwriter.
- (c) Opinion of Counsel for Underwriter. At the Closing Time, the Underwriter shall have received the favorable opinion and negative assurance letter, dated the Closing Time, of Shearman & Sterling LLP, counsel for the Underwriter in form and substance satisfactory to the Underwriter.
- (d) Officers' Certificate. At the Closing Time, there shall not have been, since the date hereof or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, and the Underwriter shall have received a certificate of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company, dated the Closing Time, to the effect that (i) there has been no such material adverse change, (ii) the representations and warranties of the Company in this Agreement are true and correct with the same force and effect as though expressly made at and as of the

Closing Time, (iii) the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied at or prior to the Closing Time, and (iv) no stop order suspending the effectiveness of the Registration Statement under the 1933 Act has been issued, no order preventing or suspending the use of any preliminary prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to their knowledge, contemplated.

- (e) Accountant's Comfort Letter. At the time of the execution of this Agreement, the Underwriter shall have received from BDO USA, LLP a letter, dated such date, in form and substance satisfactory to the Underwriter containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement, the General Disclosure Package and the Prospectus.
- (f) Bring-down Comfort Letter. At the Closing Time, the Underwriter shall have received from BDO USA, LLP a letter, dated as of the Closing Time, to the effect that they reaffirm the statements made in the letter furnished pursuant to subsection (e) of this Section, except that the specified date referred to shall be a date not more than three business days prior to the Closing Time.
- (g) Approval of Listing. At the Closing Time, the Securities shall have been approved for listing on the Nasdaq Global Select Market, subject only to official notice of issuance.
- (h) *No Objection.* FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Securities.
- (i) Lock-up Agreements. At the date of this Agreement, the Underwriter shall have received an agreement substantially in the form of Exhibit A hereto signed by the persons listed on Schedule D hereto.
- (j) Conditions to Purchase of Option Securities. In the event that the Underwriter exercises its option provided in Section 2(b) hereof to purchase all or any portion of the Option Securities, the representations and warranties of the Company contained herein and the statements in any certificates furnished by the Company and any of its subsidiaries hereunder shall be true and correct as of each Date of Delivery and, at the relevant Date of Delivery, the Underwriter shall have received:
 - (i) Officers' Certificate. A certificate, dated such Date of Delivery, of the Chief Executive Officer or the President of the Company and of the chief financial or chief accounting officer of the Company confirming that the certificate delivered at the Closing Time pursuant to Section 5(d) hereof remains true and correct as of such Date of Delivery.
 - (ii) Opinion of Counsel for Company. If requested by the Underwriter, (A) the opinion and negative assurance letter of K&L Gates LLP, counsel for the Company, and (B) the favorable opinion of Kilpatrick Townsend & Stockton LLP, intellectual property counsel for the Company, each in form and substance satisfactory to counsel for the Underwriter, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinions required by Section 5(b) hereof.
 - (iii) Opinion of Counsel for Underwriter. If requested by the Underwriter, the favorable opinion and negative assurance letter of Shearman & Sterling LLP, counsel for the Underwriter, dated such Date of Delivery, relating to the Option Securities to be purchased on such Date of Delivery and otherwise to the same effect as the opinion required by Section 5(c) hereof.

- (v) <u>Bring-down Comfort Letter</u>. If requested by the Underwriter, a letter from BDO USA, LLP, in form and substance satisfactory to the Underwriter and dated such Date of Delivery, substantially in the same form and substance as the letter furnished to the Underwriter pursuant to Section 5(f) hereof, except that the "specified date" in the letter furnished pursuant to this paragraph shall be a date not more than three business days prior to such Date of Delivery.
- (k) Additional Documents. At the Closing Time and at each Date of Delivery (if any) counsel for the Underwriter shall have been furnished with such documents and certificates as they may reasonably require for the purpose of enabling them to pass upon the issuance and sale of the Securities as herein contemplated, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Securities as herein contemplated shall be reasonably satisfactory in form and substance to the Underwriter and counsel for the Underwriter.
- (l) Termination of Agreement. If any condition specified in this Section shall not have been fulfilled when and as required to be fulfilled, this Agreement, or, in the case of any condition to the purchase of Option Securities on a Date of Delivery which is after the Closing Time, the obligations of the Underwriter to purchase the relevant Option Securities, may be terminated by the Underwriter by notice to the Company at any time at or prior to Closing Time or such Date of Delivery, as the case may be, and such termination shall be without liability of any party to any other party except as provided in Section 4 and except that Sections 1, 6, 7, 8, 15, 16 and 17 shall survive any such termination and remain in full force and effect.

SECTION 6. Indemnification.

- (a) Indemnification of Underwriter by the Company. The Company agrees to indemnify and hold harmless the Underwriter, its affiliates (as such term is defined in Rule 501(b) under the 1933 Act (each, an "Affiliate")), its selling agents and each person, if any, who controls the Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act as follows:
 - (i) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, arising out of any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rule 430B, or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or arising out of any untrue statement or alleged untrue statement of a material fact included (A) in any preliminary prospectus, any Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto), or (B) in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Securities ("Marketing Materials"), including any roadshow or investor presentations made to investors by the Company (whether in person or electronically), or the omission or alleged omission in any preliminary prospectus, Issuer Free Writing Prospectus, any Written Testing-the-Waters Communication, Prospectus or in any Marketing Materials of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading:
 - (ii) against any and all loss, liability, claim, damage and expense whatsoever, as incurred, to the extent of the aggregate amount paid in settlement of any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or of any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue

statement or omission; provided that (subject to Section 6(e) below) any such settlement is effected with the written consent of the Company; and

(iii) against any and all expense whatsoever, as incurred (including the fees and disbursements of counsel chosen by the Underwriter), reasonably incurred in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue statement or omission, or any such alleged untrue statement or omission, to the extent that any such expense is not paid under (i) or (ii) above;

provided, however, that this indemnity agreement shall not apply to any loss, liability, claim, damage or expense to the extent arising out of any untrue statement or omission or alleged untrue statement or omission made in the Registration Statement (or any amendment thereto), including information deemed to be a part thereof pursuant to Rule 430B, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.

(b) [Reserved.]

- (c) Indemnification of Company, Directors and Officers. The Underwriter agrees to indemnify and hold harmless the Company, its directors, each of its officers who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act against any and all loss, liability, claim, damage and expense described in the indemnity contained in subsection (a) of this Section, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendment thereto), including information deemed to be a part thereof pursuant to Rule 430B, the General Disclosure Package or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Underwriter Information.
- Actions against Parties; Notification. Each indemnified party shall give notice as promptly as reasonably practicable to each indemnifying party of any action commenced against it in respect of which indemnity may be sought hereunder, but failure to so notify an indemnifying party shall not relieve such indemnifying party from any liability hereunder to the extent it is not materially prejudiced (through the forfeiture of substantive rights or defenses) as a result thereof and in any event shall not relieve it from any liability which it may have otherwise than on account of this indemnity agreement. In the case of parties indemnified pursuant to Section 6(a) above, counsel to the indemnified parties shall be selected by the Underwriter, and, in the case of parties indemnified pursuant to Section 6(c) above, counsel to the indemnified parties shall be selected by the Company. An indemnifying party may participate at its own expense in the defense of any such action; provided, however, that counsel to the indemnifying party shall not (except with the consent of the indemnified party) also be counsel to the indemnified party. In no event shall the indemnifying parties be liable for fees and expenses of more than one counsel (in addition to any local counsel) separate from their own counsel for all indemnified parties in connection with any one action or separate but similar or related actions in the same jurisdiction arising out of the same general allegations or circumstances. No indemnifying party shall, without the prior written consent of the indemnified parties, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification or contribution could be sought under this Section 6 or Section 7 hereof (whether or not the indemnified parties are actual or potential parties thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising out of such litigation, investigation, proceeding or claim and (ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any indemnified party.

- (e) Settlement without Consent if Failure to Reimburse. If at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a)(ii) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.
- SECTION 7. Contribution. If the indemnification provided for in Section 6 hereof is for any reason unavailable to or insufficient to hold harmless an indemnified party in respect of any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount of such losses, liabilities, claims, damages and expenses incurred by such indemnified party, as incurred, (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, from the offering of the Securities pursuant to this Agreement or (ii) if the allocation provided by clause (i) is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and of the Underwriter, on the other hand, in connection with the statements or omissions, which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations.

The relative benefits received by the Company, on the one hand, and the Underwriter, on the other hand, in connection with the offering of the Securities pursuant to this Agreement shall be deemed to be in the same proportion as the total net proceeds from the offering of the Securities pursuant to this Agreement (before deducting expenses) received by the Company bear to the total compensation received by the Underwriter from the sale of the Securities.

The relative fault of the Company, on the one hand, and the Underwriter, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or by the Underwriter and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The Company and the Underwriter agree that it would not be just and equitable if contribution pursuant to this Section 7 were determined by pro rata allocation or by any other method of allocation which does not take account of the equitable considerations referred to above in this Section 7. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above in this Section 7 shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission.

Notwithstanding the provisions of this Section 7, the Underwriter shall not be required to contribute any amount in excess of the total compensation received by the Underwriter in connection with the Securities underwritten by it and distributed to the public.

No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the 1933 Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

For purposes of this Section 7, each person, if any, who controls the Underwriter within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act and the Underwriter's Affiliates and selling agents shall have the same rights to contribution as the Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of Section 15 of the 1933 Act or Section 20 of the 1934 Act shall have the same rights to contribution as the Company.

SECTION 8. Representations, Warranties and Agreements to Survive. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company or any of its subsidiaries submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of the Underwriter or its Affiliates or selling agents, any person controlling the Underwriter, its officers or directors or any person controlling the Company and (ii) delivery of and payment for the Securities.

SECTION 9. Termination of Agreement.

- (a) Termination. The Underwriter may terminate this Agreement, by notice to the Company, at any time at or prior to the Closing Time or any Date of Delivery (i) if there has been, in the judgment of the Underwriter, since the time of execution of this Agreement or since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package or the Prospectus, any material adverse change in the condition, financial or otherwise, or in the earnings, business affairs or business prospects of the Company and its subsidiaries considered as one enterprise, whether or not arising in the ordinary course of business, or (ii) if there has occurred any material adverse change in the financial markets in the United States or the international financial markets, any outbreak of hostilities or escalation thereof or other calamity or crisis or any change or development involving a prospective change in national or international political, financial or economic conditions, in each case the effect of which is such as to make it, in the judgment of the Underwriter, impracticable or inadvisable to proceed with the completion of the offering or to enforce contracts for the sale of the Securities, or (iii) if trading in any securities of the Company has been suspended or materially limited by the Commission or the Nasdaq Global Select Market, or (iv) if trading generally on the NYSE MKT or the New York Stock Exchange or in the Nasdaq Global Select Market has been required, by any of said exchanges or by order of the Commission, FINRA or any other governmental authority, or (v) a material disruption has occurred in commercial banking or securities settlement or clearance services in the United States or with respect to Clearstream or Euroclear systems in Europe, or (vi) if a banking moratorium has been declared by either Federal or New York authorities.
- (b) Liabilities. If this Agreement is terminated pursuant to this Section, such termination shall be without liability of any party to any other party except as provided in Section 4 hereof, and provided further that Sections 1, 6, 7, 8, 15, 16 and 17 shall survive such termination and remain in full force and effect.

SECTION 10. [Reserved.]

SECTION 11. <u>Notices</u>. All notices and other communications hereunder shall be in writing and shall be deemed to have been duly given if mailed or transmitted by any standard form of telecommunication. Notices to the Underwriter shall be directed to it at One Bryant Park, New York, New York 10036, attention of Syndicate Department (facsimile: (646) 855-3073), with a copy to ECM Legal (facsimile: (212) 230-8730), with a copy to Shearman & Sterling LLP at 599 Lexington Avenue, New York, NY 10022, attention of Ilir Mujalovic. Notices to the Company shall be directed to it at Axonics, Inc., 26 Technology Drive,

Irvine, CA 92618, attention of Aaron Pettit, General Counsel and Chief Compliance Officer; with a copy to K&L Gates LLP at 1 Park Plaza, Twelfth Floor, Irvine, CA 92614, attention of Michael A. Hedge.

SECTION 12. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Securities pursuant to this Agreement, including the determination of the purchase price of the Securities and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriter, on the other hand, and does not constitute a recommendation, investment advice, or solicitation of any action by the Underwriter, (b) in connection with the offering of the Securities and the process leading thereto, the Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, any of its subsidiaries, or its stockholders, creditors, employees or any other party, (c) the Underwriter has not assumed and will assume no advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Securities or the process leading thereto (irrespective of whether the Underwriter has advised or is currently advising the Company or any of its subsidiaries on other matters) and the Underwriter has no obligation to the Company with respect to the offering of the Securities except the obligations expressly set forth in this Agreement, (d) the Underwriter and its affiliates may be engaged in a broad range of transactions that involve interests that differ from those of each of the Company and (e) the Underwriter has not provided any legal, accounting, regulatory, investment or tax advice with respect to the offering of the Securities and the Company has consulted its own respective legal, accounting, financial, regulatory and tax advisors to the extent it deemed appropriate, and (f) none of the activities of the Underwriter in connection with the transactions contemplated herein constitutes a recommendation, investment advice or solicitation of any action by the Underwriter with respect to any entity or natural person.

SECTION 13. Recognition of the U.S. Special Resolution Regimes.

- (a) In the event that the Underwriter that is a Covered Entity becomes subject to a proceeding under a U.S. Special Resolution Regime, the transfer from the Underwriter of this Agreement, and any interest and obligation in or under this Agreement, will be effective to the same extent as the transfer would be effective under the U.S. Special Resolution Regime if this Agreement, and any such interest and obligation, were governed by the laws of the United States or a state of the United States.
- (b) In the event that the Underwriter that is a Covered Entity or a BHC Act Affiliate of the Underwriter becomes subject to a proceeding under a U.S. Special Resolution Regime, Default Rights under this Agreement that may be exercised against the Underwriter are permitted to be exercised to no greater extent than such Default Rights could be exercised under the U.S. Special Resolution Regime if this Agreement were governed by the laws of the United States or a state of the United States.

For purposes of this Section 13, a "BHC Act Affiliate" has the meaning assigned to the term "affiliate" in, and shall be interpreted in accordance with, 12 U.S.C. § 1841(k). "Covered Entity" means any of the following: (i) a "covered entity" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 252.82(b); (ii) a "covered bank" as that term is defined in, and interpreted in accordance with, 12 C.F.R. § 382.2(b). "Default Right" has the meaning assigned to that term in, and shall be interpreted in accordance with, 12 C.F.R. § 252.81, 47.2 or 382.1, as applicable. "U.S. Special Resolution Regime" means each of (i) the Federal Deposit Insurance Act and the regulations promulgated thereunder and (ii) Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act and the regulations promulgated thereunder.

SECTION 14. Parties. This Agreement shall each inure to the benefit of and be binding upon the Underwriter and the Company and their respective successors. Nothing expressed or mentioned in this Agreement is intended or shall be construed to give any person, firm or corporation, other than the Underwriter, the Company and their respective successors and the controlling persons and officers and

directors referred to in Sections 6 and 7 and their heirs and legal representatives, any legal or equitable right, remedy or claim under or in respect of this Agreement or any provision herein contained. This Agreement and all conditions and provisions hereof are intended to be for the sole and exclusive benefit of the Underwriter, the Company and their respective successors, and said controlling persons and officers and directors and their heirs and legal representatives, and for the benefit of no other person, firm or corporation. No purchaser of Securities from the Underwriter shall be deemed to be a successor by reason merely of such purchase.

SECTION 15. <u>Trial by Jury.</u> Each of the Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates), and the Underwriter hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

SECTION 16. GOVERNING LAW. THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK.

SECTION 17. Consent to Jurisdiction; Waiver of Immunity. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby shall be instituted in (i) the federal courts of the United States of America located in the City and County of New York, Borough of Manhattan or (ii) the courts of the State of New York located in the City and County of New York, Borough of Manhattan (collectively, the "Specified Courts"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court, as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum.

SECTION 18. <u>TIME</u>. TIME SHALL BE OF THE ESSENCE OF THIS AGREEMENT. EXCEPT AS OTHERWISE SET FORTH HEREIN, SPECIFIED TIMES OF DAY REFER TO NEW YORK CITY TIME.

SECTION 19. <u>Counterparts and Electronic Signatures</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement. Electronic signatures complying with the New York Electronic Signatures and Records Act (N.Y. State Tech. §§ 301-309), as amended from time to time, or other applicable law will be deemed original signatures for purposes of this Agreement. Transmission by telecopy, electronic mail or other transmission method of an executed counterpart of this Agreement will constitute due and sufficient delivery of such counterpart.

SECTION 20. Effect of Headings. The Section headings herein are for convenience only and shall not affect the construction hereof.

If the foregoing is in accordance with your understanding of our agreement, please sign and return to the Company a counterpart hereof, whereupon this instrument, along with all counterparts, will become a binding agreement between the Underwriter and the Company in accordance with its terms.

Very truly yours,

AXONICS, INC.

By :/s/ Dan Dearen
Name: Dan Dearen
Title: President and CFO

[Signature Page to Underwriting Agreement]

CONFIRMED AND ACCEPTED, as of the date first above written:

BOFA SECURITIES, INC.

By:/s/ Authorized Signatory
Authorized Signatory

[Signature Page to Underwriting Agreement]

SCHEDULE A

The purchase price per share for the Securities to be paid by the Underwriter shall be \$63.85, subject to adjustment in accordance with Section 2(b) for dividends or distributions declared by the Company and payable on the Initial Securities but not payable on the Option Securities.

| Name of Underwriter | Number of Initial Securities |
|-----------------------|---------------------------------|
| BofA Securities, Inc. | 1,750,000 |
| Total | 1,750,000 |

SCHEDULE B

[Reserved]

SCHEDULE C-1

Terms

- 1. The Company is selling 1,750,000 shares of Common Stock.
- 2. The Company has granted an option to the Underwriter to purchase up to an additional 262,500 shares of Common Stock.
- 3. The offering price as to each investor shall be the price paid by each investor.

Sch C - 1

SCHEDULE C-2

Free Writing Prospectuses

None.

Sch C - 2

SCHEDULE C-3

Written Testing-the-Waters Communication

None.

Sch C - 3

SCHEDULE D

<u>List of Persons Subject to Lock-up</u>

Alfred Ford

Dan Dearen

David Demski

Jane Kiernan

John Woock

Karen Noblett

Michael Carrel

Nancy L. Snyderman

Raymond Cohen

Robert McNamara

Rinda Sama

Esteban López

FORM OF LOCK-UP FROM DIRECTORS, OFFICERS OR OTHER STOCKHOLDERS TO BE DELIVERED PURSUANT TO SECTION 5(i)

LOCK-UP AGREEMENT

August [], 2022

BofA Securities, Inc. One Bryant Park New York, New York 10036

Re: <u>Proposed Public Offering by Axonics, Inc.</u>

Dear Ladies and Gentlemen:

The undersigned, a stockholder, and/or an officer and/or a director, as applicable, of Axonics, Inc., a Delaware corporation (the "Company"), understands that BofA Securities, Inc. (the "Underwriter") proposes to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company providing for the public offering (the "Public Offering") of shares of the Company's common stock, par value \$0.0001 per share (the "Common Stock"). In recognition of the benefit that the Public Offering will confer upon the undersigned as a stockholder, and/or an officer and/or a director, as applicable, of the Company, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with the Underwriter that, during the period beginning on the date hereof and ending on the date that is 30 days from the date of the Underwriting Agreement (the "Lock-Up Period"), the undersigned will not, without the prior written consent of the Underwriter, (i) directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of any shares of the Common Stock or any securities convertible into or exercisable or exchangeable for shares of the Common Stock, whether now owned or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (collectively, the "Lock-Up Securities"), or exercise any right with respect to the registration of any of the Lock-Up Securities, or file, cause to be filed or cause to be confidentially submitted any registration statement in connection therewith, under the Securities Act of 1933, as amended, (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of the Lock-Up Securities, whether any such swap or transaction is to be settled by delivery of shares of the Common Stock or other securities, in cash or otherwise or (iii) publicly disclose the intention to do any of the foregoing described in clauses (i) and (ii).

Notwithstanding the foregoing, and subject to the conditions below, the undersigned may transfer the Lock-Up Securities without the prior written consent of the Underwriter under the following circumstances, provided that (1) in the case of clauses (i) through (iv), the Underwriter receives a signed lock-up agreement for the balance of the Lock-Up Period from each donee, trustee, distributee, or transferee, as the case may be, (2) in the case of clauses (i) through (iv) and (vi) through (vii), any such transfer shall not involve a disposition for value, (3), in the case of clauses (i) through (iv), such transfers are not required to be reported with the Securities and Exchange Commission (the "Commission") on Form 4 in accordance with Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"),

and (4) the undersigned does not otherwise voluntarily effect any public filing or report regarding such transfers:

- (i) as a bona fide gift or gifts; or
- (ii) to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned (for purposes of this lock-up agreement, "immediate family" shall mean any relationship by blood, marriage or adoption, not more remote than first cousin); or
- (iii) as a distribution to limited partners, members or stockholders of the undersigned; or
- (iv) to the undersigned's affiliates or to any investment fund or other entity controlled or managed by the undersigned; or
- (v) to the Company (1) pursuant to the exercise, in each case on a "cashless" or "net exercise" basis, of any option to purchase Common Stock granted by the Company pursuant to any employee benefit plans or arrangements described in the prospectus relating to the Public Offering or filed as an exhibit to the registration statement, provided that any shares of Common Stock received by the undersigned upon any such exercise will be subject to the terms of this lock-up agreement, or (2) for the purpose of satisfying any withholding taxes (including estimated taxes) due as a result of the exercise of any such option to purchase Common Stock, the vesting of any restricted stock awards or the vesting and settlement of any restricted stock units granted by the Company pursuant to employee benefit plans or arrangements described in the prospectus relating to the Public Offering or filed as an exhibit to the registration statement, in each case on a "cashless" or "net exercise" basis, provided that any shares of Common Stock received by the undersigned upon any such exercise or vesting will be subject to the terms of this lock-up agreement; provided that in the case of any transfer to the Company pursuant this clause (v), such transfer is not required to be reported with the Commission in a filing under Section 16(a) of the Exchange Act, and that any shares of Common Stock received by the undersigned upon any such exercise, vesting or settlement and not transferred to the Company will be continue to be subject to the terms of this lock-up agreement; or
- (vi) pursuant to an order of a court or regulatory agency; provided that in the case of any transfer pursuant this clause (vi), any filing under Section 16(a) of the Exchange Act, shall state in the footnotes thereto that such transfer is pursuant to an order of a court or regulatory agency, unless such a statement would be prohibited by any applicable law, regulation or order of a court or regulatory authority; or
- (vii) by will or intestate succession upon the death of the undersigned; provided that in the case of any transfer pursuant to this clause (vii), any filing under Section 16(a) of the Exchange Act shall state in the footnotes thereto that such transfer is as a result of the circumstances described above; or
- (viii) in response to a *bona fide* third-party tender offer made to all holders of shares of Common Stock or in connection with a merger, consolidation, stock exchange or other similar transaction, in each case, whereby all or substantially all of the shares of Common Stock are acquired by a third party and where such transaction occurs after the consummation of the Public Offering and is approved by the board of directors of the Company; provided that, in the event that such tender offer, merger, consolidation, stock exchange or other

- similar transaction is not completed, such shares of Common Stock shall remain subject to the terms of this lock-up agreement; or
- (ix) pursuant to a 10b5-l trading plan that complies with Rule 10b5-l under the Exchange Act ("10b5-l Trading Plan") that has been entered into by the undersigned prior to the date of this lock-up agreement, provided that (x) any filing under Section 16 of the Exchange Act made during the Lock-Up Period shall clearly indicate in the footnotes thereto that the filing relates to the circumstances described above and (y) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales or transfers during the Lock-Up Period.

Notwithstanding anything herein to the contrary, nothing in this lock-up agreement shall prevent the undersigned from establishing a 10b5-1 Trading Plan or from amending an existing 10b5-1 Trading Plan so long as such newly established 10b5-1 Trading Plan or amendment to an existing 10b5-1 Trading Plan does not provide for sales of Lock-Up Securities during the Lock-Up Period; *provided* that, the establishment of a 10b5-1 Trading Plan or the amendment of a 10b5-1 Trading Plan, in either case, providing for sales of Lock-Up Securities shall only be permitted if (i) the establishment or amendment of such plan is not required to be reported in any public report or filing with the Commission, or otherwise during the Lock-Up Period, and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding the establishment or amendment of such plan during the Lock-Up Period. Notwithstanding the foregoing, if an amendment to a 10b5-1 Trading Plan (which 10b5-1 Trading Plan was entered into prior to the date of this lock-up agreement) does not increase the number of Lock-Up Securities that may be sold by the undersigned during the Lock-Up Period pursuant to clause (ix) above, the undersigned will not be prevented from selling Lock-Up Securities under such 10b5-1 Trading Plan during the Lock-Up Period to the extent such sales would otherwise be permitted by clause (ix).

Notwithstanding anything else herein, the undersigned may sell shares of the Common Stock purchased by the undersigned in the Public Offering or on the open market following the Public Offering if and only if (i) such sales are not required to be reported in any public report or filing with the Commission, or otherwise and (ii) the undersigned does not otherwise voluntarily effect any public filing or report regarding such sales.

The undersigned acknowledges and agrees that the Underwriter has not provided any recommendation or investment advice nor has the Underwriter solicited any action from the undersigned with respect to the offering of the securities and the undersigned has consulted their own legal, accounting, financial, regulatory and tax advisors to the extent deemed appropriate.

The undersigned also agrees and consents to the entry of stop transfer instructions with the Company's transfer agent and registrar against the transfer of the Lock-Up Securities except in compliance with the foregoing restrictions.

This lock-up agreement (and for the avoidance of doubt, the Lock-Up Period described herein) and related restrictions shall automatically terminate upon the earliest to occur, if any, of (i) either the Company, on the one hand, or the Underwriter, on the other hand, advising the other in writing prior to the execution of the Underwriting Agreement that it has determined not to proceed with the Public Offering, (ii) the termination of the Underwriting Agreement before the sale of any shares of the Common Stock to the Underwriting Agreement is withdrawn or (iv) September 30, 2022, in the event the closing of the Public Offering shall not have occurred on or before such date.

THIS AGREEMENT AND ANY CLAIM, CONTROVERSY OR DISPUTE ARISING UNDER OR RELATED TO THIS AGREEMENT SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF, THE STATE OF NEW YORK.

[Signature page follows]

A-4

| Very truly yours, |
|---|
| [NAME OF STOCKHOLDER/ OFFICER/ DIRECTOR] |
| By: Name: Title: |
| If not signing in an individual capacity: |
| Name of Authorized Signatory (Print) |
| Title of Authorized Signatory (Print) Idicate capacity of person signing if signing as custodian, trustee, or on behalf of an tity.) |

K&L GATES

K&L GATES LLP

1 PARK PLAZA
TWELFTH FLOOR
IRVINE, CA 92614
T+1 949 253 0900 F+1 949 253 0902 kigates.com

August 5, 2022

Axonics, Inc. 26 Technology Drive Irvine, California 92618

Ladies and Gentlemen:

We have acted as counsel to Axonics, Inc., a Delaware corporation (the "Company"), in connection with the proposed offering and sale by the Company of up to 2,012,500 shares of the Company's Common Stock, par value \$0.0001 per share (the "Common Stock") (which includes up to 262,500 shares that are subject to the underwriter's option to purchase additional shares to cover over-allotments, if any) (the "Shares"), pursuant to the Registration Statement on Form S-3 (No. 333-238064) filed by the Company with the Securities and Exchange Commission (the "Commission") under the Securities Act of 1933, as amended (the "Securities Act"), on May 7, 2020 and declared effective by the Commission on May 7, 2020, the related base prospectus dated May 7, 2020 (the "Base Prospectus"), and the prospectus supplement dated August 2, 2022 (together with the Base Prospectus, the "Prospectus"). This opinion is being furnished to you in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

You have requested our opinion as to the matters set forth below in connection with the Registration Statement, the Prospectus and the offering of the Shares thereunder. For purposes of rendering these opinions, we have examined: (i) the Registration Statement; (ii) the Prospectus; (iii) the Amended and Restated Certificate of Incorporation of the Company, as amended to date, and the Amended and Restated Bylaws of the Company, as amended to date; and (iv) the records of corporate actions of the Company relating to the Registration Statement, the Prospectus and matters in connection therewith. We have also made such other investigation as we have deemed appropriate. We have examined and relied upon certificates of public officials and, as to certain matters of fact that are material to our opinions, we have also relied on a certificate of an officer of the Company. In rendering our opinions, we have also made assumptions that are customary in opinion letters of this kind. We have not verified any of those assumptions.

Our opinions set forth below are limited to the Delaware General Corporation Law.

Based upon and subject to the foregoing, it is our opinion that the Shares are duly authorized for issuance by the Company and, when issued and paid for as described in the Prospectus, will be validly issued, fully paid and nonassessable.

We hereby consent to the filing of this opinion letter as an exhibit to the Company's Current Report on Form 8-K and to the reference to this firm in the Prospectus under the caption "Legal Matters." In giving our consent, we do not hereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations thereunder.

Yours truly, /s/ K&L Gates LLP K&L Gates LLP

Axonics® Announces Proposed Public Offering of Common Stock

IRVINE, Calif. – August 2, 2022 – Axonics, Inc. (Nasdaq: AXNX) ("Axonics"), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced that it has commenced a proposed underwritten public offering of 1,750,000 shares of its common stock. Axonics expects to grant the underwriter a 30-day option to purchase up to an additional 262,500 shares of its common stock.

Axonics anticipates using the net proceeds from the offering for working capital and general corporate purposes, including a potential \$35 million milestone payment in connection with its previously announced and completed acquisition of Contura Limited (solely to the extent that such milestone payment is finally determined to be due and payable by Axonics in accordance with the definitive agreements governing the acquisition).

BofA Securities is acting as the sole book-running manager for the offering. The offering is subject to market and other customary closing conditions, and there can be no assurance as to whether or when the offering may be completed.

The shares described above are being offered pursuant to a shelf registration statement on Form S-3, including a base prospectus, which was previously filed by Axonics with the Securities and Exchange Commission ("SEC") on May 7, 2020 and became automatically effective upon filing. A preliminary prospectus supplement and accompanying prospectus relating to the offering will be filed with the SEC and will be available on the SEC's website at www.sec.gov. When available, copies of the preliminary prospectus supplement and the accompanying prospectus may be obtained by contacting: BofA Securities, 200 North College Street, 3rd Floor, Charlotte NC 28255-0001, Attention: Prospectus Department, or by email at dg.prospectus requests@bofa.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of, these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Axonics, Inc.

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction.

Forward-Looking Statements

Statements Axonics makes in this press release may include statements which are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. Axonics intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and is making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including references to Axonics' expectations regarding the completion, timing and size of its proposed underwritten public offering, and the anticipated use of proceeds therefrom (including statements regarding the milestone payment that may become due

and payable in connection with Axonics' acquisition of Contura Limited), reflect its current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to Axonics and on assumptions it has made. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including statements regarding the proposed underwritten public offering and the risks and uncertainties disclosed in Axonics' filings with the SEC, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

Contact:

Axonics Neil Bhalodkar Investor Relations 949-336-5293 <u>ir@axonics.com</u>

Axonics® Announces Pricing of Public Offering of Common Stock

IRVINE, Calif. – August 2, 2022 – Axonics, Inc. (Nasdaq: AXNX) ("Axonics"), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced that it priced its previously announced underwritten public offering of 1,750,000 shares of its common stock. The offering is expected to close on August 5, 2022, subject to the satisfaction of customary closing conditions.

Axonics has granted the underwriter a 30-day option to purchase up to 262,500 additional shares of its common stock.

Axonics anticipates using the net proceeds from the offering for working capital and general corporate purposes, including a potential \$35 million milestone payment in connection with its previously announced and completed acquisition of Contura Limited (solely to the extent that such milestone payment is finally determined to be due and payable by Axonics in accordance with the definitive agreements governing the acquisition).

BofA Securities is acting as the sole book-running manager for the offering. BofA Securities may offer the shares from time to time for sale in one or more transactions on the Nasdaq Global Select Market, in the over-the-counter market, through negotiated transactions or otherwise at market prices prevailing at the time of sale, at prices related to prevailing market prices or at negotiated prices. The offering is subject to market and other customary closing conditions, and there can be no assurance as to whether or when the offering may be completed.

The shares described above are being offered pursuant to a shelf registration statement on Form S-3, including a base prospectus, which was previously filed by Axonics with the Securities and Exchange Commission ("SEC") on May 7, 2020 and became automatically effective upon filing. This offering is being made only by means of a prospectus supplement and the accompanying prospectus which forms a part of the effective shelf registration statement. A preliminary prospectus supplement and accompanying prospectus relating to the offering have been filed with the SEC and are available on the SEC's website located at http://www.sec.gov. Copies of the preliminary prospectus supplement and the accompanying prospectus and, when available, copies of the final prospectus supplement and accompanying prospectus relating to this offering may be obtained by contacting: BofA Securities, 200 North College Street, 3rd Floor, Charlotte NC 28255-0001, Attention: Prospectus Department, or by email at dg.prospectus requests@bofa.com.

This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of, these securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Axonics, Inc.

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction.

Forward-Looking Statements

Statements Axonics makes in this press release may include statements which are not historical facts and are considered forward-looking within the meaning of Section 27A of the Securities Act of 1933, as amended ("Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended ("Exchange Act"), which are usually identified by the use of words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "seeks," "should," "will," and variations of such words or similar expressions. Axonics intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act and Section 21E of the Exchange Act and is making this statement for purposes of complying with those safe harbor provisions. These forward-looking statements, including references to Axonics' expectations regarding the completion and timing of its underwritten public offering, and the anticipated use of proceeds therefrom (including statements regarding the milestone payment that may become due and payable in connection with Axonics' acquisition of Contura Limited), reflect its current views about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to Axonics and on assumptions it has made. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including statements regarding the underwritten public offering and the risks and uncertainties disclosed in Axonics' filings with the SEC, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Axonics undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

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Axonics® Announces Closing of Public Stock Offering and Full Exercise of Underwriter's Option to Purchase Additional Stock

IRVINE, Calif. – **August 5, 2022** – Axonics, Inc. (Nasdaq: AXNX) ("Axonics"), a global medical technology company that is developing and commercializing novel products for the treatment of bladder and bowel dysfunction, today announced the closing of its public offering of 2,012,500 shares of its common stock at a price of \$63.85 per share to the underwriter, which includes the exercise in full by the underwriter of its option to purchase 262,500 additional shares. The gross proceeds from the offering to Axonics, before deducting estimated offering expenses, were approximately \$128.5 million.

BofA Securities acted as the sole book-running manager for the offering.

The shares described above were offered pursuant to a shelf registration statement on Form S-3, including a base prospectus, which was previously filed by Axonics with the Securities and Exchange Commission ("SEC") on May 7, 2020 and became automatically effective upon filing. A final prospectus supplement and accompanying prospectus relating to this offering have been filed with the SEC and are available on the SEC's website located at http://www.sec.gov. Copies of the final prospectus supplement and accompanying prospectus relating to this offering may be obtained by contacting: BofA Securities, NC1-004-03-43, 200 North College Street, 3rd Floor, Charlotte, NC 28255-0001, Attention: Prospectus Department, or by email at dg.prospectus_requests@bofa.com. The final terms of the offering were disclosed in the final prospectus supplement filed with the SEC.

About Axonics, Inc.

Based in Irvine, Calif., Axonics is a global medical technology company that is developing and commercializing novel products for adults with bladder and bowel dysfunction.

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