Exhibit 10.13  
Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it is not  
material and is of the type that the registrant treats as private and confidential.  
Vendor Agreement  
Between  
Xxxxxx Research, Inc.  
And  
BioTE Medical, LLC  
December 1, 2020  
 1  
Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it  
is not material and is of the type that the registrant treats as private and confidential.  
 VENDOR AGREEMENT  
This Vendor Agreement (“this Agreement”) is made and entered into as of the 1st day of December 2020 (“the Effective Date”), by and between Xxxxxx Research, Inc., a South Carolina corporation (“Xxxxxx”), having its offices at 000 Xxxx Xxxxxxxxxx Xxxx., Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000, and BioTE Medical, LLC, a Texas limited liability company (“BioTE”), having its offices at 0000 Xxxx Xxxxxx Xxxx Xxxx, Xxxxx 000, Xxxxxx, Xxxxx 00000, and who are sometimes referred to individually as a “Party” or together as the “Parties.”  
WHEREAS, the Parties entered into that certain Non-Exclusive Co-Marketing Agreement, dated May 30, 2019, but the Parties now desire to replace that agreement with the terms, conditions, and obligations of this Agreement; and  
WHEREAS, Xxxxxx intends to provide product and AgeBio testing of up to [\*\*\*] toward the funding of a clinical trial to be sponsored by and conducted by BioTE and Xxxxxx; and  
WHEREAS, Xxxxxx remains engaged in the business of research, development, manufacture, distribution, and sale of a line of nutritional supplement products that promote better health and wellbeing for patients through health-care practitioners who prescribe or recommend Xxxxxx’x nutritional supplement products to their patients; and  
WHEREAS, BioTE remains engaged in the business of recruiting, training, and supporting physicians and other healthcare providers located in the United States of America or any of its territories to perform BioTE’s proprietary method of hormone balance (“BioTE Medical Hormone Pellet Therapy”) using pelletized therapeutic products derived from natural plant sources designed to replicate the body’s normal hormonal levels; and  
WHEREAS, BioTE commits to a long-term strategic partnership with Xxxxxx to grow the supplements and wellness products offering for BioTE’s 5,500 practitioners in the U.S. BioTE also commits to work with Xxxxxx to provide supplements for BioTE’s currently unserved international practitioners. BioTE has invested considerable funds and will continue to invest funds creating a market for these Xxxxxx supplements in the clinical, retail, direct to consumer, and online markets in Mexico and South America.  
WHEREAS, BioTE currently sells only to medical practitioners, BioTE is making a considerable investment in adding direct-to-patient and direct-to-consumer supplement sales. All Xxxxxx-BioTE products will be marketed to these large new markets in Q1 2021. Although BioTE’s growth with Xxxxxx has been strong in the practitioner market, it will only be a fraction of the new direct-to-patient and direct-to-consumer market. Considerable growth can also be predicted on the automatic delivery/subscription service that will be available at the start of the program in Q1 2021.  
 2  
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 WHEREAS, BioTE will continue to use Xxxxxx as a contract manufacturer for the current BioTE-labelled nutritional supplement products listed in Appendix 1, and as mutually agreed on for future nutritional supplement product development and manufacturing for BioTE-labelled nutritional supplement products and, where appropriate and mutually agreed on, recommend Xxxxxx’x nutritional supplement product line to those health-care practitioners who prescribe and recommend the BioTE Medical Hormone Pellet Therapy to their patients.  
NOW THEREFORE, the Parties agree on the following terms, conditions, and obligations as set forth herein:  
 1.  
Validation Study. The Parties anticipate that certain of BioTE’s certified healthcare providers will conduct a year-long validation study. The Parties further anticipate that Xxxxxx will provide up to, but not more than, [\*\*\*] in product and AgeBio Testing toward implementing and conducting the validation study. The Parties agree to provide an appropriate attribution to Xxxxxx’x participation and assistance in the validation study upon publication of the results of such study.  
 2.  
Term. Whereas the initial term of the Non-Exclusive Vendor Agreement was two (2) years; i.e., the term of that agreement would have expired on May 29, 2021, the initial term of this Agreement will be three (3) years; i.e., the expiration date of this Agreement will be November 30, 2023; provided, however, that either Party may terminate this Agreement at any time for business convenience by providing a 180-day written notice to the other Party.  
 3.  
Drop Ship Agreement. The Parties agree that certain Drop Ship Agreement previously agreed to and executed by the Parties on May 30, 2019 (Appendix 2) will remain in place, and the Parties agree to continue to comply with its terms, conditions, and obligations, and such Drop Ship Agreement is incorporated by reference herein. Notwithstanding the foregoing, the Parties agree that if BioTE moves from a drop ship arrangement to an agreement with a third-party logistics provider, the Parties will review and revise the Drop Ship Agreement in place to address such change in shipping arrangements.  
 4.  
Quality Agreement. The Parties agree to the terms, conditions, and obligations of the Quality Agreement attached as Appendix 3, below, which is executed by the Parties as of the Effective Date of this Agreement and is incorporated by reference herein.  
 5.  
Sales Strategies. The Parties agree to continue to use commercially reasonable efforts by Xxxxxx’x sales representatives to expose, instruct, and recommend the BioTE Medical Hormone Pellet Therapy to their health-care practitioner customers, and by BioTE to expose, instruct, and recommend BioTE-branded and Xxxxxx’x nutritional supplement product line to BioTE’s health-care practitioner customers.  
 3  
Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it  
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 6.  
Sales and Marketing Materials. The Parties agree to work together to develop sales and marketing materials to be used by Xxxxxx and BioTE, respectively, to facilitate the accomplishment of the Sales Strategies set forth in Paragraph 5, above.  
 7.  
Training. The Parties agree to make training available to each Party’s respective sales force.  
 8.  
Commission Structure. Xxxxxx agrees that if any of BioTE’s customers opt to purchase any other non-BioTE branded products, then BioTE will be entitled to receive a [\*\*\*] commission paid for on a monthly commission cycle for the other products sold, but not including previous Xxxxxx customers who have purchased product from Xxxxxx in the previous 24 months.  
 9.  
Contract Manufacturing. The Parties agree that during the Term of this Agreement, Xxxxxx will continue to be a manufacturer of the finished nutritional supplement products that bear a BioTE-branded label listed in Appendix 1, subject to the mutually agreed upon production schedule(s) for the manufacture of such products. BioTE further agrees to continue to purchase such finished products from Xxxxxx as set forth in this Agreement at such time as each lot of finished product is released for sale by Xxxxxx’x Quality Assurance/Quality Control Department, and proof of such release for sale of finished BioTE-branded product is submitted, with the lot number’s accompanying invoice, to BioTE for approval and payment. BioTE will continue to receive a weekly statement reconciling the previous week’s orders processed by Xxxxxx, which statement will continue to be emailed to BioTE each week for the previous week’s processed orders. BioTE will continue to receive a [\*\*\*] discount for payment of a statement within seven (7) days or less from the date of the statement received and be allowed to pay their invoice by credit card. BioTE will continue to have up to seven (7) days to review the statement for accuracy and make payment by credit card on or before the seventh day to receive the 1-percent early payment discount. If payment is not received by the seventh day after a statement is received by BioTE, then Xxxxxx can seek approval from BioTE to charge BioTE’s credit card on file without a discount. In the event Xxxxxx experiences an increase greater than ten percent (10%) in raw material or component costs for those items needed in order to manufacture the finished nutritional supplement products for BioTE, Xxxxxx may, upon receipt of BioTE’s prior written approval, which approval will not be unreasonably withheld, increase the purchase price of the finished nutritional supplement products manufactured for BioTE.  
 10.  
Stock. Subject to reasonably accurate and timely rolling 12-month forecasts from BioTE, as well as mutually agreed upon production schedule(s), Xxxxxx continues to commit to remain in stock on those BioTE-branded products manufactured pursuant to Paragraph 9, above. Xxxxxx agrees to provide written notice to BioTE immediately (i.e., within twenty- four (24) business hours) if an out-of-stock situation occurs, and Xxxxxx agrees to continue to pay for additional 2-day shipping at no cost to the customer or BioTE.  
 4  
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is not material and is of the type that the registrant treats as private and confidential.  
 11.  
Tracking and Billing. As the Parties deem necessary and by mutual agreement, the Parties agree to continue to develop processes to track and report the purchases of Xxxxxx’x nutritional supplement products that are consummated as a result of the implementation of the Sales Strategies contemplated in Paragraph 5, above.  
 12.  
Nutritional Supplement Products. The Parties agree that as of the Effective Date of this Agreement the nutritional supplement products that BioTE will expose to, instruct on, and recommend to their health-care practitioner customers are those listed in Appendix 1. By mutual agreement, the Parties reserve the right to add additional nutritional supplement products during the Term of this Agreement.  
 13.  
Forecasts. Xxxxxx and BioTE will continue to work closely together, and in good faith, to put in place rolling 12-month quarterly forecasts for production, which will be updated bimonthly based on historic and future trends.  
 14.  
Shipping / Returns. Xxxxxx’x modified shipping rates as agreed on by the Parties in Appendix 2 of the previous Non-Exclusive Vendor Agreement will continue to apply as the shipping rates during the Term of this Agreement, and former Appendix 2 is incorporated by reference herein as Appendix 2. Returns will continue to be addressed by the Parties on a case-by-case basis.  
 15.  
No Representations or Warranties. Neither Xxxxxx nor BioTE are authorized to make representations or warranties on behalf of the other with respect to the BioTE Medical Hormone Pellet Therapy or Xxxxxx’x nutritional supplement products, respectively, that are not otherwise contained in the sales and marketing materials contemplated by Paragraph 6, above, or otherwise authorized by the prior written consent of the Party for whom the representation or warranty might apply.  
 16.  
Regulatory Compliance and Oversight. Each Party will be solely responsible for its compliance with the applicable laws and regulations pertaining to the manufacture, marketing, and distribution of its products and services.  
 (a)  
Xxxxxx will be responsible for adverse event reporting for the Xxxxxx nutritional supplement products that BioTE recommends to its affiliated providers.  
 (b)  
Xxxxxx will be responsible for complying with the regulatory requirements, policies, and procedures associated with manufacturing, distributing, and marketing its nutritional supplement product line.  
 17.  
Product Discontinuance. Either Party may discontinue at any time, with at least one hundred twenty (120) days’ prior written notice to the other Party, any product. In the event BioTE discontinues a BioTE-branded product, then BioTE will be obligated to purchase, within one hundred eighty (180) days, any inventory of that discontinued product existing as of the date BioTE provided written notice of discontinuance.  
 5  
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 18.  
Force Majeure. Except for payments due under this Agreement, neither Party will be responsible for any failure to perform or delay in performance if such failure or delay is caused, directly or indirectly, by events or circumstances beyond such Party’s reasonable control (each a “Force Majeure”), including, but not limited to, acts of God, war, sabotage, riot, embargoes, compliance with court orders, acts of civil or military authorities, domestic or foreign acts of terrorism, denial of or delays in processing of export license applications, fire, lightening, epidemic, pandemic, floods or other severe weather conditions, earthquakes, accidents, strikes, fuel crises, interruptions or delays in transportation or communication facilities, or any other event or circumstance, whether similar or dissimilar to those set forth herein, provided that such Party gives prompt written notice thereof to the other Party and takes reasonable steps to minimize the effect of the event on such Party’s performance. The time for performance will be extended for a period equal to the duration of the Force Majeure, but in no event longer than sixty (60) days. After such time, the other Party will have the right to immediately terminate this Agreement.  
 19.  
Indemnification. Each Party agrees to indemnify the other Party and hold it harmless from all claims, demands, damages, and liabilities of any kind to the extent any such claim, demand, damage, or liability arises as a result of the implementation of their respective obligations undertaken by the Parties in the performance of this Agreement.  
 20.  
Intellectual Property; BioTE’s customers. The Parties acknowledge that each Party exclusively owns the right, title, and interest in its respective intellectual property, and that nothing in this Agreement transfers or inhibits the other Party’s exclusive ownership thereof. Without limiting the generality of the foregoing, the Parties agree that any proprietary formulations developed by BioTE will remain the sole and exclusive property of BioTE, regardless of whether BioTE utilizes Xxxxxx to manufacture or produce any such products on BioTE’s behalf. Xxxxxx acknowledges that the customers that it ships to on behalf of BioTE are part of BioTE’s intellectual property. Xxxxxx further acknowledges and agrees that it must obtain BioTE’s written approval prior to marketing any products, services, or items to BioTE’s customers. As used in this Paragraph 20, the term “marketing” will include, without limitation, electronic messaging, text messaging, telephone calls, in-person meetings, mailings, the gifting of samples, and any other advertising or soliciting of BioTE’s customers by Xxxxxx. Notwithstanding the foregoing, this prohibition does not include previous Xxxxxx customers who purchased product from Xxxxxx in the twenty-four (24) month period prior to the effective date of the Parties’ previous Non-Exclusive Vendor Agreement.  
 21.  
Confidentiality. The Parties agree that neither Party will disclose or use, without the other Party’s prior written consent, any non-public, confidential, or proprietary information of the other Party, including, but not limited to, trade secrets, product development information, business operations information, or customer information, that has been provided to the other Party in furtherance of undertaking their respective obligations.  
 6  
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is not material and is of the type that the registrant treats as private and confidential.  
 22.  
Notices. Any notice required or desired to be given pursuant to this Agreement will be deemed to have been given when such notice, in writing, is delivered to the other Party at the respective address first written above and addressed to the individual undersigned below.  
 23.  
Relationship of the Parties. Nothing contained in this Agreement will be construed as creating a joint venture, partnership, or agency relationship between the Parties, nor will either Party have the right, power, or authority to create any obligation or duty, express or implied, on behalf of the other Party.  
 24.  
Governing Law. The Parties agree that this Agreement will be governed by the laws of the State of Delaware, without regard to Delaware’s rules relating to conflicts of laws, and the Parties hereby consent to the jurisdiction of the federal and state courts of the State of Delaware relating to any action, suit, or proceeding brought to compel performance of any obligation undertaken herein by the Parties.  
 25.  
Entire Agreement; Amendments. This Agreement and attached Appendices, and the documents incorporated by reference in this Agreement, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements between the Parties with respect to its subject matter. No amendment, change, waiver, or discharge hereof will be valid unless in writing and signed by the Party against which such amendment, change, waiver, or discharge is sought to be enforced.  
[SIGNATURE PAGE FOLLOWS]  
 7  
Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it  
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 IN WITNESS WHEREOF, the Parties have executed this Vendor Agreement as of the Effective Date above written.  
 FOR XXXXXX RESEARCH, INC.  
/s/ Xxxx X. Xxxxxxxx  
By: Xxxx X. Xxxxxxxx  
Its: Chief Executive Officer  
FOR BIOTE MEDICAL, LLC  
/s/ Xxxxx Xxxxx  
By: Xxxxx Xxxxx  
Its: Chief Executive Officer  
 8  
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 Appendix 1  
Current BioTE-labelled Nutritional Supplement Products  
Methyl Guard Plus  
Meriva 500 SF  
DIM SGS +  
ADK 5  
ADK 10  
FloraSport Probiotic  
Iodine  
Omega w/CoQ10  
Bacillus Coagulans  
 9  
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 Appendix 2  
Shipping Provisions  
All shipping of BioTE products will be coordinated through Xxxxx’x Shipping Department, who will be responsible for determining and administering the most cost-effective and timely means of transit.  
Orders will be processed for fulfillment from 8:30 am to 7:00 pm ET (4 pm PT).  
Within the continental U.S., the following shipping terms will apply:  
 ●   
Free shipping (delivery within 1 to 3 business days of order) for any order of 1 case or more.  
 ●   
1-day air will be billed to BioTE at [\*\*\*] per shipment.  
Shipments to Hawaii will be billed to BioTE at [\*\*\*], with delivery being 3 business days from pick-up.  
The Shipping Department will also coordinate International shipments as required.  
 ●   
For Canada — BioTE will be charged [\*\*\*] per shipment with delivery within 3 business days of order.  
 ●   
For Puerto Rico, the U.S. Virgin Islands and other Caribbean locations — BioTE will be charged [\*\*\*] per shipment with delivery within 3 business days of order.  
Discounts for Order Processing for BioTE 3PL  
During the term of this agreement, if and when BioTE elects uses their own third party logistics provider (3PL) for order fulfillment, Xxxxxx agrees to a [\*\*\*] per bottle discount as Xxxxxx will no longer be required provide order processing (pick-pack-ship) direct to Clinics or Patients, and only ship in bulk quantities to the selected BioTE 3PL.  
 10  
Certain identified information marked with [\*\*\*] has been excluded from this exhibit because it  
is not material and is of the type that the registrant treats as private and confidential.  
 Appendix 3  
Quality Agreement  
This Quality Agreement (“this Agreement”) is made as of the 1st day of December 2020, by and between:  
Xxxxxx Research, Inc. (“Xxxxxx”) having a principal place of business at 000 Xxxx Xxxxxxxxxx Xxxx., Xxxxxxxxxxx, Xxxxx Xxxxxxxx 00000, with an FDA Food Facility Registration Number of 11647265648,  
and  
BioTE Medical, LLC (“BioTE”) having a principal place of business at 0000 Xxxx Xxxxxx Xxxx Xxxx, Xxxxx 000, Xxxxxx, Xxxxx 00000.  
WHEREAS, BioTE has contracted with Xxxxxx to provide manufacturing services in respect of certain Products (as set forth in Exhibit 1 of this Agreement) (the “Products”); and  
WHEREAS, the parties desire to allocate the responsibility for procedures and Specifications, as defined below in Section 1.1 and set out in Exhibit 1 herein, impacting on the identity, strength, quality, and purity of the Products.  
NOW THEREFORE, in consideration for the promises and agreements contained herein, the parties agree as follows:  
 1.0  
GENERAL REQUIREMENTS  
 1.1  
Specifications  
Both parties acknowledge that Xxxxxx’x and BioTE’s businesses and operations are regulated by the U.S. Food and Drug Administration (“FDA”) and therefore agree to comply with the requirements of this Agreement and the Specifications. For purposes of clarity, the terms and conditions of this Agreement will apply to the Products set forth in Exhibit 1, as well as any future products manufactured by Xxxxxx on behalf of BioTE.  
 1.2  
Division of Responsibilities  
This Agreement defines the responsibilities of Xxxxxx and BioTE for assuring compliance with current Good Manufacturing Practices (21 CFR Part 111), and quality activities associated with production, packaging, testing, and release of Products (“cGMPs”).  
 11  
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is not material and is of the type that the registrant treats as private and confidential.  
 1.3  
Business Terms  
This Agreement does not define the business terms relating to the commercial supply of Products. To the extent there is conflict or inconsistency between the provisions of this Agreement and a BioTE purchase order and/or the Non-Exclusive Co-Marketing Agreement between Xxxxxx and BioTE, the terms of the Purchase Order and/or such Non-Exclusive Co-Marketing Agreement will govern with respect to the terms and conditions relating to the business and commercial supply requirements for Products.  
 1.4  
Attached Exhibits  
Listed below are the following Exhibits that are attached hereto and incorporated into this Agreement:  
Exhibit 1 — Products and Specifications  
 2.0  
REGULATORY COMPLIANCE  
 2.1  
Product and Facility Compliance  
Xxxxxx will itself manufacture, except for as set forth in Section 15.0, Products in accordance with the requirements of cGMPs.  
Xxxxxx will conduct manufacturing operations in accordance with current cGMP guidelines and accepted industry practices during the term of this Agreement. These requirements include maintaining a quality assurance system and facility that complies with and satisfies the requirements of 21 CFR Part 111, or an equivalent standard, where applicable, for any electronic records and computer systems.  
Xxxxxx and BioTE are responsible for complying with the regulatory requirements that are specifically set forth in this Agreement or the Division of Responsibilities.  
 2.2  
Compliance: Audits  
Xxxxxx may be periodically audited upon reasonable notice by BioTE or an approved BioTE agent for compliance to current cGMPs and BioTE requirements and to assess the effectiveness of Xxxxxx’x quality system. Xxxxxx will allow BioTE reasonable access to the facility, to appropriate personnel, and to relevant documents, including laboratory testing notebooks. The cost of such audit will be borne by BioTE. Trade secret documents that relate to formulas and manufacturing processes will need approval from Xxxxxx’x Chief Operating Officer prior to sharing documents with BioTE. Documents will not be transmitted electronically, but can be viewed as hard copies during compliance audits.  
 12  
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 2.3  
FDA Food Facility Registration  
Xxxxxx is responsible to register its manufacturing facility with the FDA and to maintain the registration documents such that they are readily available for inspection, as the case may be.  
Xxxxxx’x current FDA Food Facility Registration Number is 11647265648.  
 2.4  
Regulatory Inspections  
Xxxxxx will notify BioTE’s Quality Control of any regulatory inspections and state or federal correspondence (which include, but are not limited to, FDA Form 483s, FDA Warning Letters, and FDA or state board inspection reports, among others) concerning Product quality within three (3) business days or sooner. Xxxxxx will also provide a copy of any such inspection reports or copies of any correspondence received from state or federal regulators to BioTE within three (3) business days or sooner per lawyer client privileges.  
BioTE will notify Xxxxxx of any regulatory inspections that BioTE is subject to that implicate Xxxxxx or involve any of Xxxxxx’x products manufactured under BioTE’s label, and Xxxxxx agrees to be immediately available by telephone to provide any appropriate documentation that BioTE will need to satisfy the inspection. BioTE to provide a copy of inspection reports related to Xxxxxx manufactured products within three business days of receiving the final report.  
 2.5  
Qualifications and Training  
Procedures will be established by Xxxxxx to assure that all personnel are adequately educated and routinely trained according to cGMP regulations and job functions.  
Xxxxxx will maintain and record training documents, and will provide evidence of personnel qualification and routine training to BioTE immediately upon request.  
 3.0  
CONTROL DOCUMENTATION AND CHANGE CONTROL  
 3.1  
Control Documentation  
Xxxxxx will maintain on site a system of written quality procedures, manufacturing instructions, and facility operations that reflect the processes set forth in the specifications. In addition, Xxxxxx will, in accordance with cGMPs, maintain a change management system that tracks and controls changes to such documents.  
 13  
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is not material and is of the type that the registrant treats as private and confidential.  
 3.2  
Change Control  
Xxxxxx will provide BioTE with at least thirty (30) days’ prior written notice of any significant changes that have potential effects on the quality and/or marketing authorization of the products listed within this document. Change requests will confirm that product characteristics will be unaffected and will be supported by technical documentation. Significant changes to product manufacturing or packaging processes, equipment, production sites, tests, or specifications that would require regulatory approval or notification must be mutually agreed upon in writing by Xxxxxx and BioTE.  
The parties mutually agree to make changes to the Products and Specifications (as listed on Exhibit 1) to comply with cGMPs or any governmental guidelines. Xxxxxx agrees to implement any changes to the extent such changes are necessary to comply with cGMPs and any governmental guidelines.  
 3.3  
Other Changes  
Xxxxxx will provide at least thirty (30) days’ prior written notice to BioTE of any proposed changes relating to the storage or shipment of Products, as well as any planned changes in any facilities or equipment that may impact the manufacturing of Products.  
 4.0  
CERTIFICATE OF ANALYSIS AND CERTIFICATE OF COMPLIANCE  
 4.1  
Certificate of Analysis  
Xxxxxx will maintain Certificates of Analysis (“COA”) for each batch of Product delivered, and will make such COAs available to BioTE upon request. In accordance with 21 CFR § 111.75, BioTE will rely on the information provided in the COA provided that:  
 (a)  
Xxxxxx qualifies the supplier by establishing the reliability of the supplier’s certificate of analysis through confirmation of the results of the supplier’s tests or examinations;  
 (b)  
The COA includes a description of the test or examination method(s) used, label claim specifications, and actual results of the tests or examinations;  
 (c)  
Xxxxxx maintains documentation of how Xxxxxx qualified the supplier, and forwards such documentation to BioTE upon BioTE’s request;  
 (d)  
Xxxxxx periodically re-confirms the supplier’s COA; and  
 (e)  
Xxxxxx’x quality control personnel reviews and approves the documentation setting forth the basis for qualification (and re-qualification) of any supplier.  
 14  
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 The COA must specify the Product, specifications, including (if available) label claim, expiration date, and results for the particular lot, and when applicable will include test method reference and the signature of the person authorized to release the lot. Xxxxxx will provide copies of internal and external test data sheets and chromatograms for applicable analytical tests on request for investigations or as necessary.  
Xxxxxx will include with the COA any record of investigation report prepared in response to an unplanned deviation or out-of-specification test result.  
 4.2  
Xxxxxx Information  
Xxxxxx will identify knowledgeable and qualified professionals readily accessible who will provide information and respond to queries, as follows:  
 (a)  
Notify BioTE in writing of any regulatory agency communications or contacts related to the Products and provide a copy of documents requested and left by the authorities within one (1) business day.  
 (b)  
Notify BioTE in writing of stability trends or non-conformance to specification within three (3) business days.  
 (c)  
Provide an investigation report for adverse events within 30 business days of Xxxxxx’x receipt of such complaints, or immediately upon completion of the investigation report, whichever is sooner.  
 (d)  
Meet with BioTE, as necessary, to discuss technical matters relating to the manufacture of Products.  
 (e)  
Advise BioTE in writing of major unplanned process deviations or confirmed out-of-specification results within one (1) business day of Xxxxxx’x knowledge of the same.  
 (f)  
Provide a COA (via electronic mail to BioTE’s QA department) for each finished batch shipment of Product.  
 5.0  
INVESTIGATIONS OF DEVIATIONS  
 5.1  
Deviations  
Xxxxxx will investigate thoroughly any unplanned deviation from approved procedures or out-of-specification test results, or any deviation that results from noncompliance with 21 C.F.R. § 101.9(g)(4)(i), that is, a deviation that results when the nutrient content of the composite is not formulated to be at least equal to the value for that nutrient declared on the product’s label. Such investigation must adhere to an approved written procedure and be documented. Review and approval of such investigation by Xxxxxx’x Quality Assurance is required prior to disposition or disposal of the Product, if required and necessary. No Product involved in an investigation may be distributed or released to BioTE until the investigation is completed.  
 15  
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 5.2  
Notification and Report  
Xxxxxx must inform BioTE in writing of any major planned deviation, major unplanned deviation, or confirmed out-of-specification result affecting a Product’s quality after manufacturing or packaging, and submit to BioTE an investigation plan prior to completion of the investigation. Examples of situations that require an investigation and report include: (i) Confirmed out-of-specification laboratory result; (ii) major process deviation; (iii) failure of equipment that affects a Product; and (iv) significant yield deviation in or between bulk, packaged Product, and labeling.  
A report on root cause of the problem and corrective action/preventative action plan is due within thirty (30) calendar days of the discovery of any major process deviation or confirmed out of specification result.  
 6.0  
PRODUCT TESTING  
 6.1  
Written Procedures  
Xxxxxx will have and follow written procedures in place for sampling and testing each batch of the Product prior to release. Such procedures include the following:  
 (a)  
Examination of a representative sample of units during packaging operations for correct labeling.  
 (b)  
Laboratory test records for conformance to Specifications, including identity, strength, purity, and potency of selected dietary ingredients.  
 (c)  
Current and approved validated test methods and acceptance criteria at the end of manufacturing.  
 (d)  
Sampling plans based on commonly accepted statistical criteria.  
Upon request, Xxxxxx will provide BioTE with written procedures for samples and testing the product. Xxxxxx will allow BioTE the opportunity to request different and/or additional sampling and product testing only for investigation purposes  
 16  
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is not material and is of the type that the registrant treats as private and confidential.  
 6.2  
Approval by a Qualified Professional  
No batch of Product will be released to BioTE prior to approval by a qualified professional. Xxxxxx will appoint a qualified professional who will ensure that Products meeting BioTE’s Specifications are released to BioTE.  
 7.0  
OBSOLETE, WASTE, AND REJECTED MATERIALS DISPOSITION  
 7.1  
Destruction Procedures  
Xxxxxx will certify destruction of any excess, expired, obsolete, or rejected Products or raw materials. Xxxxxx will provide a Certificate of Destruction attesting that such Products or materials were destroyed at BioTE’s request (“COD”).  
 7.2  
Environmental Laws  
Xxxxxx will comply with federal, state, and local applicable environmental and safety laws and regulations pertaining to handling of any waste arising from the manufacture of Products.  
 8.0  
PRODUCT COMPLAINT MANAGEMENT  
Xxxxxx will comply with all review and investigation process requirements as set forth in the sections below and in 21 CFR 111.  
 8.1  
Product Complaints  
Xxxxxx or BioTE may be notified of complaints received by customers or consumers of the Product. For purposes of this Agreement, “Routine Complaints” include any complaint that is not life threatening and includes, without limitation, short product count, incorrect address, and delayed shipments. If and when Xxxxxx or BioTE receives a Routine Complaint, the receiver of such a Routine Complaint must notify the other party within 72 hours, unless such complaint is an Urgent Complaint as defined below. These include complaints received either verbally or in a written format for both Urgent Complaints and Routine Complaints.  
For purposes of this Agreement, “Urgent Complaints” include any complaint that alleges an adverse event; adulteration, contamination, tampering, misbranding, mislabeling, lack of stability, or that may reasonably be interpreted as having significant safety or regulatory consequences. With respect to Urgent Complaints, Xxxxxx will notify BioTE of receipt of an Urgent Complaint immediately, and not less than 24 hours after receipt. Further, Xxxxxx will respond to BioTE inquiries in writing immediately upon BioTE’s receipt of an Urgent Complaint, and not less than 24 hours after receipt.  
 17  
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 8.2  
Procedures for Complaints  
The procedures for handling Product complaints must address recording, managing, and investigating complaints, and the party responsible for recording, reporting, and investigating Product complaints will forward such Product complaints to the other party.  
Xxxxxx will comply with all reasonable requests made by BioTE in connection with a Product complaint, the procedures for managing Product complaints, and the investigation thereof of any Product.  
 8.3  
Maintaining Records  
A written record of each Product complaint will be received and maintained in accordance with cGMPs, FDA guidelines, and Xxxxxx’x policy for handling Product complaints. A reasonable attempt should be made to obtain and document the following information on each Product complaint record:  
 (a)  
Complainant’s name and address, unless the complainant wishes to remain anonymous.  
 (b)  
Name, strength and dosage form of the Product.  
 (c)  
Lot number and expiration date.  
 (d)  
Date complaint received and Product returned.  
 (e)  
Nature of the complaint.  
 (f)  
Complaint tracking (identification) number.  
 8.4  
Storage of Product Returned  
BioTE samples that contain Product (“BioTE Samples”) will be provided by BioTE to Xxxxxx for purposes of complaint investigations, if available.  
Xxxxxx will document receipt of BioTE Sample(s) in the complaint record and will maintain BioTE Samples in a secure location.  
 8.5  
Investigation  
All Routine and Urgent Complaints received by either BioTE or Xxxxxx regarding any of the Products require an investigation. For Routine and Urgent Complaints, the investigation plan, outline, or list of action steps must be submitted to BioTE. The investigations may be wholly or partially executed by Xxxxxx but must minimally include provisions for:  
 18  
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 (a)  
Manufacturing record review.  
 (b)  
In-Process and Finished Product test results review.  
 (c)  
Shipping and distribution controls review.  
 (d)  
Packaging record review.  
 (e)  
Review of complaint and associated files for detection of trends.  
 (f)  
Review of impact on other Product or additional lots of the same Product.  
 (g)  
Testing of returned or reserve Product as necessary.  
Investigations on Urgent Complaints will be initiated immediately with a target completion date of seven (7) calendar days. An investigation report must be issued inclusive of results of all testing performed, data reviews, and trend discoveries, with a conclusion and corrective action/preventative action plan recommendations, as required, at the close of an investigation. A copy of the final report must be kept on file by Xxxxxx as part of the complaint record. Final investigation reports must be forwarded to BioTE within three (3) business days of completion.  
Product testing on returned or retained samples in the custody of Xxxxxx is at the discretion of Xxxxxx. BioTE may request that Xxxxxx perform Product testing; however, Xxxxxx will follow its own written procedures for testing returned or retained samples. Any returned or retained samples sent to Xxxxxx not consumed by required testing will be returned to BioTE.  
 9.0  
RECALL  
Xxxxxx will have sole responsibility for initiating and managing any recall of BioTE’s Products manufactured or procured by Xxxxxx. BioTE will be informed prior to the initiation of a recall to the extent that such recall arises out of a breach of its obligations hereunder.  
There will be timely exchange of information between Xxxxxx and BioTE about any potential recall, as follows:  
 (a)  
Xxxxxx will immediately inform BioTE in writing of any circumstances that have come to its attention that may make a recall necessary.  
 (b)  
In the event a Regulatory Authority issues or requests a recall, Xxxxxx or BioTE will, within 24 hours, notify the other party.  
 19  
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 (c)  
Within 48 hours of learning that a recall may be necessary, Xxxxxx and BioTE will discuss details of the recall strategy.  
BioTE will require a COD should Product be returned to Xxxxxx as the result of a recall.  
Xxxxxx will pay BioTE all reasonable, out-of-pocket, costs, expenses, and attorneys’ fees borne by BioTE in connection with any recall of Xxxxxx’x products manufactured under BioTE’s label, or in connection with any recall of product whose manufacturing process was outsourced by Xxxxxx but bearing BioTE’s label.  
 10.0  
RECORDS AND RETAINED SAMPLES RETENTION  
Xxxxxx will hold, in a secure manner, original records and representative samples from the manufacture and control of each lot of Product. Product samples must be stored under controlled and labeled conditions. All production history documentation will be available to BioTE for inspection while onsite. Electronic records will satisfy the requirements of 21 CFR Part 111 or an equivalent standard, where applicable.  
 10.1  
Retained Samples  
Retained samples to be kept per Xxxxxx’x internal procedure and will be provided to BioTE upon BioTE’s request.  
 10.2  
Records  
Xxxxxx to follow internal document retention schedule per policy document POL-00001.  
 11.0  
REPROCESSING/ REWORKING  
The parties will mutually agree in advance of plans to rework or reprocess Product unless an already agreed on procedure exists and there are no trends, or as permitted by the terms set forth in this Section. No change will be made to a validated process without the prior written authorization of BioTE. Xxxxxx may not reprocess Product, unless reprocessing to correct defects of the type that from time to time arise during a packaging run (e.g., jams which damage secondary packaging) due to machine capabilities. Such routine reprocessing must be documented in the packaging record.  
Xxxxxx will have written procedures that describe the system for reworking or reprocessing Product. The system must provide for trending and include corrective and preventive action. Product recovery will be in keeping with the agreed upon procedure and documented. For Product to be considered releasable, all predetermined Specifications and other quality criteria must be met.  
 20  
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 12.0  
SELF-INSPECTION  
Xxxxxx will maintain a written program of self-inspection by technical personnel for all cGMP areas, as follows:  
 (a)  
Inspections will be conducted at least annually in keeping with a schedule. Xxxxxx will provide documentation of such inspections to BioTE upon BioTE’s written request.  
 (b)  
The persons performing the inspection should be knowledgeable in their respective fields and familiar with cGMP.  
 (c)  
A report must be made of the observations.  
 (d)  
Management must evaluate the observations and corrective action.  
 (e)  
If applicable, an agreed upon corrective action must be initiated and tracked.  
 (f)  
A record of the observations and corrective actions will be maintained by Xxxxxx, a copy of which will be forwarded to BioTE upon request.  
 13.0  
STABILITY TESTING AND BEST-USED-BY DATING  
Xxxxxx and BioTE will mutually agree on procedures for determining Best-Use-By Dating for purchased BioTE products. Xxxxxx will provide BioTE with a written explanation of the data to be used for determining Best-Use-By dates for each item. For all private-label products where full stability testing has been performed on the finished product, Xxxxxx will provide BioTE with a copy of the final summary report upon request. BioTE may contract with Xxxxxx additional stability testing of finished Products at BioTE’s expense. That stability testing program will be in writing and include the following elements:  
 (a)  
Product specific stability protocols that detail sample size, analytical/test methods including known and unknown impurity profiles and limits, (if applicable), test intervals, storage condition(s), packaging components/configurations and reason for the study  
 (b)  
Stability-indicating test methods  
 (c)  
Criteria for batch selection for the program  
 (d)  
Secure, alarmed, and qualified storage  
 (e)  
Manual and/or electronic data collection  
 (f)  
Statistical analysis capability  
 21  
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 (g)  
Out-of-specification investigation and notification mechanism  
 (h)  
Data summarization and distribution  
Xxxxxx will follow its SOP-00212 “Stability Testing Program.”  
 14.0  
STORAGE AND SHIPPING CONDITIONS  
Xxxxxx will store manufactured Products in defined areas under appropriate conditions of temperature, humidity, and light and in accordance with specifications such that quality is not affected. In addition, Xxxxxx will have written procedures that describe storage, handling and distribution of the Product and minimally address:  
 (a)  
Periodic verification of actual storage conditions at Xxxxxx’x facility.  
 (b)  
Storage of semi-finished or finished Product under controlled labeled conditions.  
 (c)  
Handling of Product that has been subjected to improper storage conditions.  
 (d)  
Selection and preparation of Product for shipment.  
 (e)  
Monitoring to ensure shipping conditions have been maintained where requirements exist.  
 15.0  
SUBCONTRACTING  
In the event that a Purchase Order authorizes Xxxxxx the right to subcontract Product manufactured, tested, or processed, such contractor must meet cGMP standards and BioTE’s regulatory requirements. Xxxxxx must ensure that the subcontractor’s personnel are adequately educated and routinely trained according to cGMP regulations and job functions, in accordance with Section 2.6 above. Xxxxxx must notify BioTE which aspects of manufacturing will be subcontracted and what manufacturing facilities will be used when initial product manufacturing quotes are provided. BioTE agrees this information will be kept confidential and will only be used for meeting cGMP compliance obligations. Xxxxxx will provide results of audits of subcontracted manufacturing facilities to BioTE on request.  
 16.0  
AMENDMENTS  
This Agreement may only be modified by a writing signed by duly authorized representatives of Xxxxxx and BioTE. The failure of either party to insist on strict performance of any provision of this Agreement, or to exercise any right or remedy, will not be deemed a waiver of such performance, right or remedy, of that or any other provision of this Agreement.  
 22  
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 17.0  
ADDITIONAL TERMS AND CONDITIONS  
If this paragraph is initialed by Xxxxxx and BioTE, then this Agreement is supplemented by the additional terms and conditions contained in the attached Exhibit 1 ( ), ( ).  
 18.0  
FACSIMILIE SIGNATURE  
The Parties agree that a facsimile signature will be deemed an original.  
IN WITNESS WHEREOF, the parties have duly executed this Quality Agreement as of the date first written above and is effective until termination of the Vendor Agreement between Xxxxxx and BioTE.  
 FOR BIOTE MEDICAL, LLC  
/s/ Xxxxx Xxxxx  
Name: Xxxxx Xxxxx  
Title: Chief Executive Officer  
 FOR XXXXXX RESEARCH, INC.  
/s/ Xxxx X. Xxxxxxxx  
Name: Xxxx X. Xxxxxxxx  
Title: Chief Executive Officer  
 23  
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is not material and is of the type that the registrant treats as private and confidential.  
 Appendix 4  
Products and Specifications to be included on Certificate of Analysis  
 Product   
Description  
 Label Claim  
 Exp  
Date  
 Test  
Results  
 Test  
Method  
Reference  
 Signature  
and Date  
ADK5 Capsule/Off-White   
Vitamin A (as Retinyl Palmitate) 1.5mg  
 Vitamin D (as D3) 5,000 IU  
 125mcg  
 Vitamin K (as MK04 and MK07)  
 500mcg  
 Per exp date printed on bottle TBD HPLC Released for use by:  
ADK10 Capsule/Off- White   
Vitamin A (as Retinyl Palmitate) 1.5mg  
 Vitamin D (as Vitamin D3) 10,000 IU  
 250mcg  
 Vitamin K (as MK-4 and MK-7)  
 500mcg  
 Per exp date printed on bottle TBD HPLC Released for use by:  
 24  
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 Iodine Plus Capsule/Off-White   
Iodine (as Potassium Iodide)  
 12.5mg  
 Zinc (as Zinc Amino Acid Chelate)  
 10mg  
 Selenium (as L-Selenomethionine)  
 200mcg  
 XXX XXX HPLC Released for use by:  
DIM Capsule/Light Xxxxx   
Diindolylmethane (as Crystalline DIM  
 150mg  
 POM Pomegranate extract (whole fruit) (Punica granatum)  
 100mg  
 Sulforaphane Glucosinolate (from broccoli extract (seed) (Brassica oleracea italica))  
 25mg  
 24 months from date of production TBD HPLC Released for use by:  
 25  
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 Omega 3+ XxX00 Xxxxxx/Xxxxxx   
EPA (Eicosapentaenoic Acid) (from Fish Oil)  
 450mg  
 DHA (Docosahexaenoic Acid) (from Fish Oil)  
 180mg  
 Coenzyme Q10  
 30mg  
 Per exp date printed on bottle TBD HPLC Released for use by:  
Methyl Factors Plus Capsule/Light Orang   
Riboflavin (as Riboflavin 5’- Phosphate Sodium)  
 90mg  
 Vitamin 6 (as Pyridoxal 5’-Phosphate)  
 45mg  
 Vitamin B12 (as Methylcobalamin)  
 3mg  
 Betain Anhydrous (Trimethylglycine)  
 1.8 g  
 Per exp date printed on bottle TBD HPLC Released for use by:  
Curcumin SF Capsule/Orange   
Curcumin Phytosome (Curcuma longa extract (root)/Phospholipid complex from Sunflower)  
 1g  
 Per exp date printed on bottle TBD HPLC Released for use by:  
 26  
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 Multi Strain Probiotic 208 Capsule/White   
HOWARU\* Restore II Blend  
 20 Billion CFUs  
 •  Bifidobacterium lactis (Bi-07) 5 Billion CFUs  
 •  Lactobacillus acidphilus (NCFM) 5 Billion CFUs  
 •  Bifidobacterium lactis (bi-04) 5 Billion CFUs  
 •  Lactobacillus paracasei (Lpc-37) 5 Billiob CFUs  
 Per exp date printed on carton TBD HPLC Released for use by:  
Bacillus Coagulans Probiotic Capsule/White   
Bacillus Coagulans  
 133mg  
 2 Billion CFUs  
 XXX XXX HPLC Released for use by:  
 27