



January 11, 2024

Via Electronic Mail: R3DNMSMAIL.Resource@nrc.gov

Materials Licensing Branch
Attn: Robert Orlikowski
U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Rd., Suite 210
Lisle, IL 60532-4352

**SUBJECT: Application for Consent of Indirect Transfer of Control:
Radioactive Materials License No. 13-35699-01MD (Docket No. 030-39337)**

Dear Sir:

Pursuant to Section 184 of the Atomic Energy Act of 1954, as amended (“AEA”), and 10 CFR § 30.34(b) and the U.S. Nuclear Regulatory Commission (“NRC”) Radioactive Materials License No. 13-35699-01MD (the “License”), RayzeBio, Inc., a Delaware corporation (“RayzeBio”), and Bristol-Myers Squibb Company, a Delaware corporation (“Bristol-Myers Squibb”) (collectively with RayzeBio, the “Applicants”), hereby request consent for the indirect transfer of the License from RayzeBio to Bristol-Myers Squibb, in order to permit continuity of operations following the proposed merger of Rudolph Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of Bristol-Myers Squibb (“Purchaser”), with and into RayzeBio.

Under a contemplated transaction between RayzeBio and Bristol-Myers Squibb, Purchaser will commence a tender offer to purchase all outstanding shares of RayzeBio common stock for a purchase price of \$62.50 per share in cash (for an aggregate all-cash transaction value of approximately \$4.1 billion) (the “Offer”) and Bristol-Myers Squibb will subsequently implement a merger of Purchaser with and into RayzeBio, with RayzeBio continuing as the surviving corporation and as a wholly owned subsidiary of Bristol-Myers Squibb (the “Merger”). Immediately after the consummation of the Merger: (i) RayzeBio will continue to operate as RayzeBio but as a wholly owned subsidiary of Bristol-Myers Squibb; (ii) the License will continue to be held by RayzeBio; and (iii) the current board of directors for RayzeBio will be replaced by Konstantina Katcheves, Sandra Ramos-Alves and Kimberly M. Jablonski, each of which are current employees of Bristol-Myers Squibb and serve as members on the board of directors of Purchaser. Attachment 1 hereto presents a simplified organizational chart illustrating the ownership of RayzeBio before and after the consummation of the Offer and the Merger.

The only substantive change to the License is the transfer of ownership of RayzeBio to Bristol-Myers Squibb. The transaction will not impact control over licensed activities. The public health and safety are not compromised by the use of the materials covered by the License. Following the closing of the Offer and the Merger (the “Closing”), the day-to-day operations under the License will remain unchanged, with operations taking place at the same location and using the same materials, facility, and procedures – all under the same facility Radiation Safety Officer.

The Applicants intend to close the transaction as promptly as practicable. The Applicants respectfully request that consent be issued no later than February 20, 2024 in order to permit continuity of operations following the anticipated closing of the proposed merger.

The requested approval timeline is important to the Applicants so that the Applicants can promptly move forward with development of RayzeBio's radiopharmaceutical therapeutics intended to treat various cancers that are resistant to multiple types of more conventional therapies.

RayzeBio is a widely held, publicly traded (NYSE: RYZB), Delaware corporation with its headquarters located in San Diego, California, and with a manufacturing facility in Indianapolis, Indiana. RayzeBio is a vertically integrated radiopharmaceutical therapeutics company with a lead program in late-stage clinical development.

Bristol-Myers Squibb is a widely held, publicly traded (NYSE: BMY), Delaware corporation with a 12-member board of directors that consists of ten U.S. citizens (one of whom is also a citizen of Italy), one citizen of Spain (with permanent residence in the U.S.) and one citizen of the United Kingdom, and with its headquarters located in Princeton, New Jersey. No entity owns more than 10 percent interest in Bristol-Myers Squibb. The Vanguard Group, Inc. ("Vanguard") holds approximately 9.8 percent of the outstanding shares of capital stock of Bristol-Myers Squibb but does not have any representation on the board of directors of Bristol-Myers Squibb. Per Vanguard's website, Vanguard is a passive American investment management company with over \$7 billion of assets under management, and its headquarters are located in Valley Forge, Pennsylvania. Bristol-Myers Squibb and its subsidiaries and affiliates are "known entities" for NRC purposes. Bristol-Myers Squibb and its subsidiaries and affiliates currently hold multiple licenses in California, New Jersey and Massachusetts (including California Materials License No. 5951-37, Amendment No. 41), which they manage in accordance with Agreement State requirements and pursuant to Agreement State oversight.

Bristol-Myers Squibb plans to finance the transaction primarily through a new debt issuance. The Closing is not conditioned on Bristol-Myers Squibb's ability to finance the transaction.

To assist in the NRC's review of the Merger, Attachment 2 hereto presents the information generally required by the NRC for transfer of control applications under its guidance in NUREG-1556, Volume 15, Revision 1, Chapter 5 and Appendix E. The attachment provides more information about the transaction.

If you have any questions or comments pertaining to this application, please contact RayzeBio's counsel for nuclear regulatory matters, M. Stanford Blanton, at Balch & Bingham LLP (205-226-3417, sblanton@balch.com).

Enclosures: Attachment 1, Simplified Organizational Chart Describing the Transaction

Attachment 2, NUREG-1556, Volume 15, Revision 1, Chapter 5 (Change of Control) and Appendix E (Information Needed for Transfer of Control Application)

cc: Tammy Tomczak, Licensing Assistant NRC Region III
 Cassandra Frazier, Radiation Health Physicist, NRC Region III
 Matthew Hadden, Corporate Radiation Safety Officer, RayzeBio, Inc.
 M. Stanford Blanton, Balch & Bingham LLP
 Daniel McDonald, Corporate Radiation Safety Officer, Bristol-Myers Squibb Company

I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the information contained in the above application pertaining to RayzeBio, Inc. is true and correct.

Executed on January 11, 2024

Kenneth Song

Kenneth Song, M.D.
Chief Executive Officer
RayzeBio, Inc.
5850 West 80th Street
Indianapolis, IN 46278

I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the information contained in the above application pertaining to Bristol-Myers Squibb Company and its subsidiaries and affiliates is true and correct.

Executed on January 11, 2024



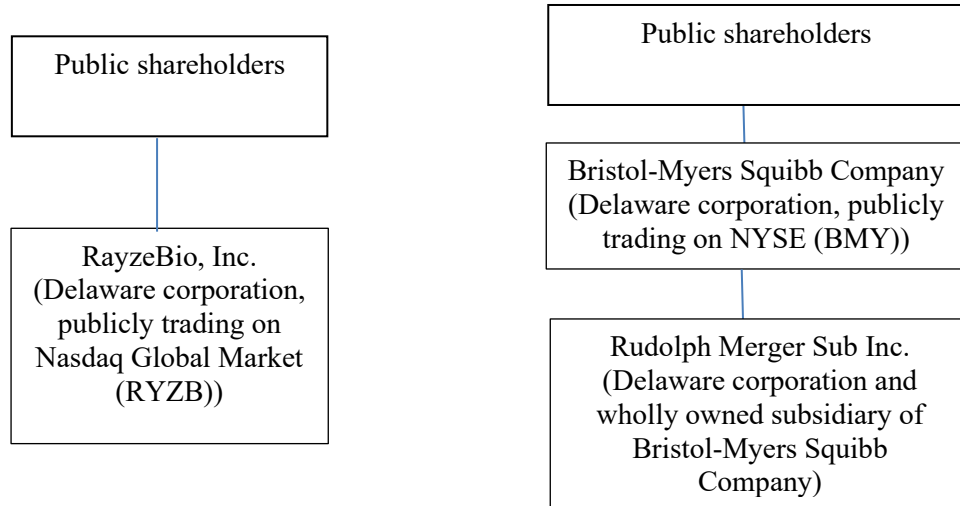
Kimberly M. Jablonski
Corporate Secretary
Bristol-Myers Squibb Company
Route 206 & Province Line Road
Princeton, New Jersey 08540

Attachment 1

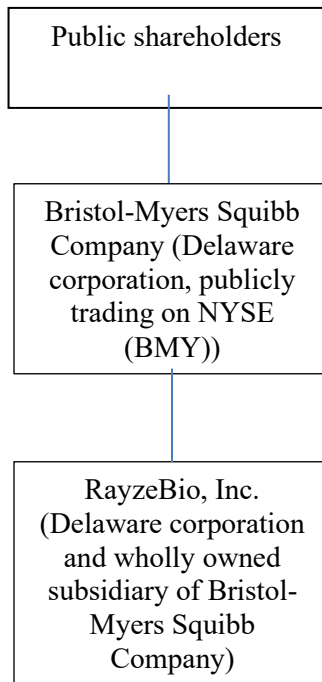
Simplified Structure Chart Illustrating Ownership of RayzeBio

Simplified Structure Chart Illustrating Ownership of RayzeBio

Pre-Transaction Structure



Post-Transaction Structure



Attachment 2

**NUREG-1556, Volume 15, Revision 1, Chapter 5 (Change of Control) and
Appendix E (Information Needed for Transfer of Control Application)**

This information is submitted consistent with Chapter 5 (Change of Control) and Appendix E (Information Needed for Transfer of Control Application) of NUREG-1556, Vol. 15, Rev. 1, *Consolidated Guidance About Materials Licenses: Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses*.

1. ***Describe any planned changes in the organization, including but not limited to, transfer of stocks or assets and mergers, change in members on Board of Directors, etc. Provide the new licensee name, mailing address, and contact information, including phone numbers. Clearly identify when the amendment request is due to a name change only.***

RayzeBio, Inc. (“RayzeBio”) currently holds U.S. Nuclear Regulatory Commission (“NRC”) Radioactive Materials License No. 13-35699-01MD (the “License”).

As part of a proposed merger pursuant to an agreement and plan of merger signed on December 25, 2023, by and between RayzeBio and Bristol-Myers Squibb Company (“Bristol-Myers Squibb” and, together with RayzeBio, the “Applicants”), Rudolph Merger Sub Inc., a Delaware corporation and a wholly owned subsidiary of Bristol-Myers Squibb (“Purchaser”), will commence a tender offer to purchase all outstanding shares of RayzeBio common stock and Bristol-Myers Squibb will subsequently implement a merger of Purchaser with and into RayzeBio (the “Merger”), resulting in an ownership change of RayzeBio. Immediately post-Merger, (i) RayzeBio will continue to operate as RayzeBio but as a wholly owned subsidiary of Bristol-Myers Squibb and (ii) the current board of directors for RayzeBio will be replaced by Konstantina Katcheves, Sandra Ramos-Alves and Kimberly M. Jablonski, each of which are current employees of Bristol-Myers Squibb and serve as members on the board of directors of Purchaser. Attachment 1 hereto presents a simplified organizational chart illustrating the ownership of RayzeBio before and after the consummation of the Offer and the Merger.

The only planned substantive change relevant to control of the License is the transfer of ownership of the licensee, RayzeBio, to Bristol-Myers Squibb. The transaction is not expected to impact control over licensed activities. The public health and safety are not compromised by the use of the materials covered by the License. Post-Merger, the day-to-day operations under the License are expected to remain unchanged, with operations taking place at the same location and using the same materials, facility, and procedures – all under the same facility Radiation Safety Officer.

The Applicants intend to close the transaction as promptly as practicable. The Applicants respectfully request that consent be issued no later than February 20, 2024 in order to permit continuity of operations following the anticipated closing of the proposed merger.

Prompt consent is important to the parties so that they can swiftly move forward with development of RayzeBio’s radiopharmaceutical therapeutics intended to treat various cancers that are resistant to multiple types of more conventional therapies.

2. ***Describe any changes in personnel or duties that relate to the licensed programs. Include training and experience for new personnel and any changes in the training program.***

There are no anticipated changes in personnel or duties relating to the licensed programs nor any anticipated changes to the existing training programs.

- 3. Describe any changes in the location, facilities, equipment, radiation safety programs, use, possession, waste management, or other procedures that relate to the licensed program.***

There are no anticipated changes to the location, facilities, equipment, radiation safety program, use, possession, waste management, or other procedures that relate to the licensed program in connection with the indirect transfer.

- 4. Describe the status of the licensee's facilities, equipment, and radiation safety program, including any known contamination and whether decontamination will occur prior to transfer. Include the status of calibrations, leak tests, area surveys, wipe tests, training, quality control, and related records.***

RayzeBio's regulated facility, equipment, and radiation safety program are in compliance with NRC regulations as of the date on the License application and each subsequent letter. RayzeBio is also in compliance with respect to calibrations, leak tests, areas surveys, wipe tests, training, quality control, and related records. Further, there is no known contamination which would require decontamination prior to the transfer.

- 5. If current decommissioning funding plans (DFP) will be changed as a result of the transfer, the revised DFP should be submitted. If other financial assurance documents will be changed as a result of the transfer, confirm that all financial assurance instruments associated with the license will be held in the transferee's name before the license is transferred, and as required by 10 CFR 30.35(f), the licensee must, within 30 days, submit financial instruments reflecting such changes.***

The pending decommissioning funding plan awaiting review by the NRC for the Indianapolis facility will not be changed as a result of the transfer. Further, financial instruments associated with the License will not be changed upon consummation of the Merger.

- 6. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to the regulator, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.***

The Applicants confirm that the records concerning the safe and effective decommissioning of the facility, which are current and will be current at the time of the transfer, will remain with RayzeBio, which will continue to hold the License.

- 7. Confirm that both transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and that the***

transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions.

The Applicants confirm that they have agreed to the indirect transfer. There are no open inspection items or enforcement actions pertaining to licensed activities.

8. ***Confirm that the transferee will abide by all constraints, conditions, requirements, representations, and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.***

RayzeBio will remain the licensee after the transfer and will continue to abide by all constraints, conditions, requirements, representations and commitments identified in and attributed to existing licensed activities after closing of the transaction. To the extent applicable, Bristol-Myers Squibb agrees to abide by all constraints, conditions, requirements, representations and commitments identified in and attributed to existing licensed activities after closing of the transaction.

9. ***The transferee, in the case of fuel cycle facilities, shall provide documentation showing that it is financially qualified to conduct normal operations. The information can be in the form of income statements and balance sheet forecasts.***

This question is not applicable to the licensed activities.

Martha Pavon

From: Tammy Tomczak
Sent: Thursday, January 11, 2024 1:25 PM
To: Martha Pavon
Cc: Sandy Pavon
Subject: FW: Application for NRC Consent to Indirect Transfer of Materials License # 13-35699-01MD (Docket No. 030-39337)
Attachments: RayzeBio Transfer of Control Application (Final).pdf

Good afternoon, Martha 😊

Can you please add the attached to ADAMS?

Thank you!!
Tammy

From: Blanton, Stan <SBLANTON@balch.com>
Sent: Thursday, January 11, 2024 11:24 AM
To: R3-DRSSMail Resource <R3-DRSSMail.Resource@nrc.gov>; Bob Orlikowski <Robert.Orlikowski@nrc.gov>; Tammy Tomczak <Tammy.Tomczak@nrc.gov>; 'cassandra.frazier@nrc.com' <cassandra.frazier@nrc.com>
Cc: 'Palaniappa, Sangitha' <spalaniappa@cooley.com>; Beerle, Ben <bbeerle@cooley.com>; Park, Rowook <rpark@cooley.com>; Jeff Woodley <jwoodley@rayzebio.com>; Matthew Hadden <mhadden@rayzebio.com>; Eric Bischoff <ebischoff@rayzebio.com>; Akkerman, Gustavo <gakkerman@cov.com>; Farkas, Susan <Susan.Farkas@bms.com>; Danielle.Menture@bms.com; McClure, Tyler A <TMcClure@cooley.com>; LeJeune, Peter <plejeune@balch.com>; Long, Kelsi <klong@balch.com>; 'Daniel.McDonald@bms.com' <Daniel.McDonald@bms.com>
Subject: [External_Sender] Application for NRC Consent to Indirect Transfer of Materials License # 13-35699-01MD (Docket No. 030-39337)

All

Attached is the application RayzeBio, Inc., as licensee-indirect transferor, and Bristol Myers Squibb, as indirect transferee for NRC consent to the indirect transfer of license # 13-35699-01MD (Docket No. 030-39337). We would very much appreciate it if you would acknowledge receipt of the application by reply to this email.

Please do not hesitate to contact me if you have any questions or if there are any issues in transmission.

Stan Blanton

M. Stanford Blanton
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