UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

SCHEDULE TO

Tender Offer Statement under Section 14(d)(1) or 13(e)(1)
of the Securities Exchange Act of 1934

89bio, Inc.
(Name of Subject Company (Issuer))

Bluefin Merger Subsidiary, Inc.
(Offeror)
A wholly owned subsidiary of

Roche Holdings, Inc.
(Parent of Offeror)

Common Stock, par value $0.001 per share
(Title of Class of Securities)

282559103
(CUSIP Number of Class of Securities)

Roger Brown
Roche Holdings, Inc.
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(Name, Address, and Telephone Numbers of Person Authorized to Receive Notices and Communications on Behalf of Filing Persons)

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☒ Check the box if the filing relates solely to preliminary communications made before the commencement of a tender offer.

Check the appropriate boxes below to designate any transactions to which the statement relates:

- ☒ third-party tender offer subject to Rule 14d-1.
- ☐ issuer tender offer subject to Rule 13e-4.
- ☐ going-private transaction subject to Rule 13e-3.
- ☐ amendment to Schedule 13D under Rule 13d-2.

Check the following box if the filing is a final amendment reporting the results of the tender offer: ☐

If applicable, check the appropriate box(es) below to designate the appropriate rule provision(s) relied upon:

- ☐ Rule 13e-4(i) (Cross-Border Issuer Tender Offer)
- ☐ Rule 14d-1(d) (Cross-Border Third-Party Tender Offer)

This filing relates solely to preliminary communications made before the commencement of a tender offer by Bluefin Merger Subsidiary, Inc., a Delaware corporation ("Merger Sub"), a wholly owned subsidiary of Roche Holdings, Inc., a Delaware corporation ("Roche"), for all of the outstanding common stock of 89bio, Inc., a Delaware corporation ("89bio"), to be commenced pursuant to the Agreement and Plan of Merger, dated as of September 17, 2025, by and among Roche, Merger Sub and 89bio.

IMPORTANT ADDITIONAL INFORMATION AND WHERE TO FIND IT

The tender offer for the outstanding shares of common stock of 89bio described in this filing has not yet commenced. This filing and the communications contained in it are for informational purposes only and do not constitute a recommendation, an offer to purchase or a solicitation of an offer to sell 89bio's securities. The solicitation and offer to purchase 89bio's shares of common stock will only be made pursuant to an offer to purchase and related tender offer materials. At the time the tender offer is commenced, Roche and Merger Sub will file a Tender Offer Statement on Schedule TO with the Securities and Exchange Commission (the "SEC") and thereafter, 89bio will file a Solicitation/Recommendation Statement on Schedule 14d-9 with the SEC with respect to the tender offer. The tender offer materials (including the Offer to Purchase, a related Letter of Transmittal and other tender offer documents) and the Solicitation/Recommendation Statement on Schedule 14d-9 will contain important information.

INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT, AS MAY BE AMENDED FROM TIME TO TIME, CAREFULLY WHEN THEY BECOME AVAILABLE PRIOR TO MAKING ANY DECISIONS WITH RESPECT TO WHETHER TO TENDER THEIR SHARES IN THE TENDER OFFER BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION, INCLUDING THE TERMS AND CONDITIONS OF THE TENDER OFFER.

The tender offer materials and the Solicitation/Recommendation Statement will be filed with the SEC, and investors and stockholders may obtain a free copy of these materials (when available) and other documents filed by Roche and 89bio with the SEC at the website maintained by the SEC at www.sec.gov. Free copies of the offer to purchase, the related letter of transmittal and certain other offering documents will be made available by Roche and when available may be obtained by directing a request to the Information Agent for the tender offer which will be named in the Tender Offer Statement on Schedule TO. Investors and stockholders may also obtain free copies of the documents filed with the SEC by 89bio on the investor relations page of 89bio's internet website at https://ir.89bio.com.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This filing may include statements that are not statements of historical fact, or "forward-looking statements," within the meaning of the federal securities laws, including with respect to Roche's proposed acquisition of 89bio. Any express or implied statements that do not relate to historical or current facts or matters are forward-looking statements. These statements are generally identified by words or phrases such as "believe", "anticipate", "expect", "intend", "plan", "will", "may", "should", "estimate", "predict", "project," "strategy," "potential", "continue" or the negative of such terms or other similar expressions. Such statements include, but are not limited to, the ability of Roche and 89bio to complete the transactions contemplated by the merger agreement, including each party's ability to satisfy the conditions to the consummation of the offer contemplated thereby and the other conditions set forth in the merger agreement, statements about the expected timetable for completing the transaction, the parties' beliefs and expectations and statements about the benefits sought to be achieved in Roche's proposed acquisition of 89bio, the potential effects of the acquisition on both Roche and 89bio and the possibility of any termination of the merger agreement. These statements are based upon the current beliefs and expectations of Roche and 89bio's management and are subject to significant risks and uncertainties. There can be no guarantees that the conditions to the closing of the proposed transaction will be satisfied on the expected timetable if at all. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements, and you should not place undue reliance on these statements.

Risks and uncertainties include, but are not limited to, uncertainties as to the timing of the offer and the subsequent merger; uncertainties as to how many of 89bio's stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the offer and the merger contemplated by the merger agreement may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the tender offer or the subsequent merger; the ability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing; the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on 89bio's business; the possibility that the milestone payments related to the contingent value right will never be achieved and that no milestone payment may be made; and the risk of legal proceedings being brought in relation to the transactions and the outcome of such proceedings, including the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability. The foregoing factors should be read in conjunction with the risks and cautionary statements discussed or identified in 89bio's public filings with the SEC, including the "Risk Factors" section of 89bio's Annual Report on Form 10-K for the year ended December 31, 2024 and subsequent Quarterly Reports on Form 10-Q, Form 8-K and in other public filings 89bio makes with the SEC from time to time as well as the tender offer materials to be filed by Roche and Merger Sub and the Solicitation/Recommendation Statement to be filed by 89bio, in each case as amended by any subsequent filings made with the SEC.

Neither Roche nor 89bio undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law.

Item 12. Exhibits

Exhibit No.	Description
99.1	Media Release issued by Roche Holdings, Inc. on September 18, 2025
99.2	Q&A Acquisition of 89bio, Inc. dated September 18, 2025

Media & Investor Release

Roche enters into a definitive merger agreement to acquire 89bio, and its phase 3 FGF21 analog for the therapy of moderate to severe MASH

- **89bio's pegozafermin allows for a potentially best-in-disease treatment for moderate to severe Metabolic Dysfunction-Associated Steatohepatitis (MASH), one of the most prevalent comorbidities of obesity**
- **Acquisition supports Roche's strategy as it enhances the company's portfolio in cardiovascular, renal, and metabolic diseases (CVRM) and offers optionality for future combination development**
- **Roche to acquire 89bio for US$14.50 per share in cash at closing, representing a total equity value of approximately US$2.4 billion. Stockholders would also receive a non-tradeable contingent value right (CVR) for up to an aggregate of US$6.00 per share in cash, representing a total deal value of up to approximately US$3.5 billion**

Basel, 18 September 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has entered into a definitive merger agreement to acquire 89bio, Inc. (Nasdaq: ETNB), a publicly listed clinical-stage biopharmaceutical company pioneering the development of innovative therapies for the treatment of liver and cardiometabolic diseases. 89bio's pegozafermin is a FGF21 analog currently in late-stage development for MASH in moderate and severe fibrotic patients (F2 and F3 stages) as well as cirrhotic patients (F4 stage). The transaction is expected to close in the fourth quarter of 2025.

This acquisition underscores Roche's dedication to advancing innovative therapies in cardiovascular, renal, and metabolic diseases (CVRM), especially for patients affected by overweight, obesity, and related health challenges such as MASH. Pegozafermin offers a distinct mechanism of action that not only holds the potential for enhanced efficacy and tolerability but also unlocks opportunities for future combination development with incretins, creating synergies with Roche's CVRM portfolio. Acquiring 89bio, therefore, fosters Roche's activities to build a robust and differentiated pipeline that targets additional causes of metabolic disease.

"This acquisition further strengthens our portfolio in cardiovascular, renal, and metabolic diseases and offers opportunities to explore combinations with existing programmes in our pipeline," said Thomas Schinecker, Roche Group CEO. "We are highly encouraged by pegozafermin's potential to become a transformative treatment option in MASH, one of the most prevalent comorbidities of obesity, and to meet diverse patient needs associated with this complex disease. With its combined anti-fibrotic and anti-inflammatory mechanism, pegozafermin could potentially offer best-in-disease efficacy for all moderate to severe MASH patients."

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89bio's pegozafermin is a glycoPEGylated analog of fibroblast growth factor 21 (FGF21) specifically designed to address critical unmet needs in MASH. With its anti-fibrotic and anti-inflammatory mechanism of action combined with a favourable safety profile, pegozafermin is positioned to potentially deliver best-in-disease efficacy for patients suffering from moderate to severe liver fibrosis (F2/F3 stages) and cirrhotic MASH (F4 stage).

Current 89bio employees will join the Roche Group as part of Roche's Pharmaceuticals Division.

Terms of the Agreement

Under the terms of the merger agreement, Roche will promptly commence a tender offer to acquire all of the outstanding shares of 89bio common stock at a price of US$14.50 per share in cash at closing, plus a non-tradeable CVR to receive certain milestone payments of up to an aggregate of US$6.00 per share in cash, representing a total equity value of approximately US$2.4 billion at closing and representing a total deal value of up to US$3.5 billion. The price payable at closing represents a premium of approximately 52% to 89bio's 60-day VWAP price on 17 September 2025. The merger agreement has been unanimously approved by the boards of Roche and 89bio.

89bio will file a recommendation statement containing the unanimous recommendation of the 89bio board that 89bio's stockholders tender their shares pursuant to the tender offer. Following the completion of the tender offer, Roche will acquire all remaining shares at the same price of US$14.50 per share in cash, plus a non-tradeable CVR to receive certain milestone payments of up to an aggregate of US$6.00 per share in cash, through a second-step merger.

Each non-tradeable CVR will entitle its holders to receive the following contingent cash payments, conditioned upon the achievement of certain commercial milestones, within specified time periods:

1. US$2.00 per share in cash, upon the first commercial sale of pegozafermin in F4 MASH cirrhotic patients (by March 31, 2030)
2. US$1.50 per share in cash, upon pegozafermin reaching annual net sales globally of at least US$3.0 billion in any calendar year (by December 31, 2033)
3. US$2.50 per share in cash, upon pegozafermin reaching annual net sales globally of at least US$4.0 billion in any calendar year (by December 31, 2035)

There can be no assurance that any payments will be made with respect to the CVR. Assuming all of the conditions of the CVR are met, this would represent additional cash consideration of up to approximately US$1.0 billion for 89bio's stockholders.

The transaction is expected to close in the fourth quarter of 2025. It is subject to customary closing conditions, including the tender of at least a majority of the outstanding shares of 89bio's common stock and the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

Citi is acting as exclusive financial advisor to Roche and Sidley Austin LLP is acting as legal counsel to Roche. Moelis & Company LLC and Centerview Partners LLC are serving as financial advisors to 89bio and Gibson, Dunn & Crutcher LLP is serving as legal counsel.

About Metabolic Dysfunction-Associated Steatohepatitis (MASH)

Metabolic Dysfunction-Associated Steatohepatitis (MASH), a serious and increasingly prevalent form of fatty liver disease, is strongly associated with the global rise in obesity and type 2 diabetes.[1] It is estimated that 5 - 7% of the world's adult population is affected by MASH1, and more than 75% of those living with the condition experience comorbidities such as overweight, obesity, and type 2 diabetes.[2] MASH is progressive and, when left untreated, can progress to cirrhosis, liver decompensation, and even to hepatocellular carcinoma.

About 89bio

89bio is a clinical-stage biopharmaceutical company dedicated to the development of best-in-class therapies for patients with liver and cardiometabolic diseases who lack optimal treatment options. The Company is in Phase 3 trials for its lead candidate, 89bio's pegozafermin, for the treatment of metabolic dysfunction-associated steatohepatitis (MASH) with advanced fibrosis, including patients with compensated cirrhosis, and severe hypertriglyceridemia (SHTG). Pegozafermin is a specifically engineered, potentially best-in-class fibroblast growth factor 21 (FGF21) analog with unique glycoPEGylated technology that optimizes biological activity through an extended half-life. The company is headquartered in San Francisco. For more information, visit www.89bio.com.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information, please visit www.roche.com.

References

1 Diabetes Care 2025;48(7):1057–1082

2 Front Cell Dev Biol. 2024 Jul 16;12:1433857. Doi: 10.3389/fcell.2024.1433857

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The tender offer materials and the Solicitation/Recommendation Statement will be filed with the SEC, and investors and stockholders may obtain a free copy of these materials (when available) and other documents filed by Roche and 89bio with the SEC at the website maintained by the SEC at www.sec.gov. Free copies of the offer to purchase, the related letter of transmittal, and certain other offering documents will be made available by Roche, and when available, may be obtained by directing a request to the Information Agent for the tender offer, which will be named in the Tender Offer Statement on Schedule TO. Investors and stockholders may also obtain free copies of the documents filed with the SEC by 89bio on the investor relations page of 89bio's website at www.89bio.com.

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Risks and uncertainties include, but are not limited to, uncertainties as to the timing of the offer and the subsequent merger; uncertainties as to how many of 89bio 's stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the offer and the merger contemplated by the merger agreement may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the tender offer or the subsequent merger; the ability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing; the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on 89bio's business; the possibility that

the milestone payments related to the contingent value right will never be achieved and that no milestone payments may be made; and the risk of legal proceedings being brought in relation to the transactions and the outcome of such proceedings, including the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability. The foregoing factors should be read in conjunction with the risks and cautionary statements discussed or identified in 89bio's public filings with the SEC, including the "Risk Factors" section of 89bio's Annual Report on Form 10-K for the year ended December 31, 2024 and subsequent Quarterly Reports on Form 10-Q, Form 8-K and in other filings 89bio makes with the SEC from time to time as well as the tender offer materials to be filed by Roche and its acquisition subsidiary and the Solicitation/Recommendation Statement to be filed by 89bio, in each case as amended by any subsequent filings made with the SEC.

Neither Roche nor 89bio undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law.

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Acquisition of 89bio | Q&A

KEY MESSAGES

About the Deal

- Roche entered into a definitive merger agreement to acquire 89bio, a publicly listed clinical-stage company pioneering the development of 89bio's pegozafermin for the treatment of moderate to severe MASH (Metabolic Dysfunction-Associated Steatohepatitis).
- With 89bio's pegozafermin, Roche aims to address metabolic dysfunction-associated steatohepatitis (MASH), one of the most prevalent comorbidities of obesity besides type 2 diabetes.
- This acquisition reaffirms our commitment to advancing therapy options in cardiovascular, renal, and metabolic (CVRM) diseases, addressing critical patient needs and high disease burden, as science gives us an opportunity to evolve the standard of care.

Why Pegozafermin

- MASH, which stands for Metabolic Dysfunction-Associated Steatohepatitis, is a severe form of liver disease that is becoming increasingly prevalent worldwide. This is largely driven by the global rise in obesity and type 2 diabetes, as most (>75%) of MASH patients also live with overweight, obesity and/or type 2 diabetes. Today, MASH is estimated to affect about 5 - 7% of the world's adult population.
- Pegozafermin is an FGF21 (Fibroblast Growth Factor 21) analog with a distinct mode of action and a favourable safety profile for MASH, designed to balance efficacy and a long dosing interval. With its combined anti-fibrotic and anti-inflammatory mechanism, pegozafermin shows the potential to become a transformative therapy option offering best-in-disease efficacy and tolerability for moderate to severe MASH patients (F2/F3/F4).
- Based on available clinical data, we see the potential for pegozafermin to be a best-in-disease FGF21 monotherapy while also expanding into combination therapies (e.g., with GLP-1 analogs), thus creating synergies with Roche's CVRM portfolio.

Potential for Roche:

- Acquiring 89bio, with its pegozafermin currently in Phase 3, offers a strong strategic fit with Roche's CVRM therapeutic area and overall strategy. The addition of 89bio's pegozafermin will support the expansion of our robust portfolio in CVRM into MASH while offering optionality for future combination development, creating synergies with Roche's CVRM portfolio.
- Our ambition is to complement and strengthen our existing CVRM portfolio programs, aiming to address the critical challenges of highly prevalent obesity-related comorbidities such as MASH, across moderate to severe disease stages by tapping into the potential of this FGF21 analog.

All questions from media must be directed to Group Media Relations media.relations@roche.com

Q&A

Deal terms and background

1. What is the rationale for this acquisition?

   - Roche entered into a definitive merger agreement to acquire 89bio, a publicly listed clinical-stage company pioneering the development of 89bio's pegozafermin for the treatment of moderate to severe MASH (Metabolic Dysfunction-Associated Steatohepatitis).
   - With this transaction, Roche reinforces its commitment to patients with cardiovascular, renal, and metabolic (CVRM) diseases, driving further advancements in addressing critical unmet patient needs in overweight, obesity, and related comorbidities.
   - With pegozafermin, Roche aims to tap into the full potential of this FGF21 analog to address MASH as one of the most prevalent comorbidities of obesity besides type 2 diabetes.

2. What is the scope of this agreement?

   Roche entered into a definitive merger agreement to acquire 89bio, a publicly listed clinical-stage company pioneering the development of pegozafermin for the treatment of moderate to severe MASH (Metabolic Dysfunction-Associated Steatohepatitis). Upon closing of the transaction, Roche will integrate 89bio. We currently envisage that 89bio's current employees will join Roche's Pharmaceuticals Division post-closing.

3. What are the financial terms of the agreement?

   Under the terms of the merger agreement, Roche will promptly commence a tender offer to acquire all of the outstanding shares of 89bio common stock at a price of US$14.50 per share in cash at closing, plus a non-tradeable CVR to receive certain milestone payments of up to an aggregate of US$6.00 per share in cash, representing a total equity value of approximately US$2.4 billion at closing and representing a total deal value of up to US$3.5 billion. The price payable at closing represents a premium of approximately 52% to 89bio's 60-day VWAP price on 17 September 2025. The merger agreement has been unanimously approved by the boards of Roche and 89bio.

   89bio will file a recommendation statement containing the unanimous recommendation of the 89bio board that 89bio's stockholders tender their shares pursuant to the tender offer. Following the completion of the tender offer, Roche will acquire all remaining shares at the same price of US$14.50 per share in cash, plus a non-tradeable CVR to receive certain milestone payments of up to an aggregate of US$6.00 per share in cash, through a second-step merger.

   Each non-tradeable CVR will entitle its holder to receive the following contingent cash payments, conditioned upon the achievement of certain commercial milestones, within specified time periods:

   1. US$2.00 per share in cash, upon the first commercial sale of pegozafermin in F4 MASH cirrhotic patients (by March 31, 2030)
   2. US$1.50 per share in cash, upon pegozafermin reaching annual net sales globally of at least US$3.0 billion in any calendar year (by December 31, 2033)
   3. US$2.50 per share in cash, upon pegozafermin reaching annual net sales globally of at least US$4.0 billion in any calendar year (by December 31, 2035)

There can be no assurance that any payments will be made with respect to the CVR. Assuming all of the conditions of the CVR are met, this would represent additional cash consideration of up to approximately US$1.0 billion for 89bio's stockholders.

4. What is the potential you see in this deal?

- MASH, which stands for Metabolic Dysfunction-Associated Steatohepatitis, is a form of liver disease that is becoming increasingly prevalent worldwide, largely driven by the global rise in obesity and type 2 diabetes as most (>75%) of MASH patients also live with overweight, obesity and/or type 2 diabetes as comorbidities. Today, MASH is estimated to affect about 5 - 7% of the world's adult population.
- Pegozafermin is an FGF21 (Fibroblast Growth Factor 21) analog with a distinct mode of action engineered to balance efficacy and a twice-monthly dosing interval. With its promising combined anti-fibrotic and anti-inflammatory mechanism associated with a favourable safety profile, Pegozafermin shows the potential to become a transformative therapy option offering best-in-disease efficacy and tolerability for patients with F2-F4 MASH.
- Acquiring 89bio, with its pegozafermin currently in Phase 3, supports Roche's strategy as it enhances our portfolio in cardiovascular, renal, and metabolic diseases (CVRM) and offers optionality for future combination development creating synergies with Roche's current CVRM portfolio

5. Did Roche shareholders have to vote for this, as it represents a significant investment?

Approval by Roche's shareholders is not required.

6. Who are the transaction financial advisors?

- Citi is acting as exclusive financial advisor to Roche, and Sidley Austin LLP is acting as legal counsel to Roche.

7. Please describe the details of the transaction. What are the conditions for a public tender offer in the United States? What are the timelines?

- The closing of the tender offer will be subject to a majority of 89bio's outstanding shares being tendered in the tender offer and other customary closing conditions for a transaction of this nature. Promptly following completion of the tender offer, Roche will acquire all remaining shares at the same price per share through a second-step merger.
- Furthermore, the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions.
- The closing of the transaction is expected to take place in the fourth quarter 2025.

8. When do you expect the transaction to close? Do you expect any prolonged regulatory reviews?

The closing of the transaction is subject to regulatory approvals and other customary closing conditions. The parties expect that the transaction will close in the fourth quarter of 2025.

9. What conditions need to be met for this transaction to be completed?

The closing of the tender offer will be subject to the tender of a number of shares that represents a majority of the total number of outstanding shares. Furthermore, the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. The closing of the transaction is currently expected to take place in the fourth quarter of 2025.

10. Will you increase your price? Are you aware of other bidders for 89bio?

We do not speculate on other bidders. We believe that our offer price is attractive.

11. Why did you include a significant CVR component given the upfront premium?

We see significant strategic opportunity in 89bio's pegozafermin and based our analysis on fundamental value, not premium. We believe that the overall offer price, including the CVR component, is an attractive package for 89bio's stockholders.

12. How long do you expect the tender offer to last? By when shall it be concluded?

The tender offer is required to be open for a minimum of 20 business days. The transaction is expected to close in Q4 2025. The transaction is also subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions.

13. Will a squeeze-out follow the public takeover offer? How many shares need to be in Roche's possession for a squeeze-out to happen?

The squeeze-out, or second-step merger, will be effected promptly after the closing of the tender offer. It requires that a majority of the outstanding 89bio shares have been tendered in the offer.

14. Will this transaction be core EPS dilutive?

No.

15. Regarding any questions on, e.g., IRR, ROI, peak sales, additional interest expense due to financing, etc.?

We do not disclose these figures.

Strategic fit and potential for Roche

16. How does this acquisition fit into Roche's CVRM strategy?

- Acquiring 89bio, with its pegozafermin currently in Phase 3, offers a strong strategic fit with our CVRM therapeutic area and overall strategy. The addition of pegozafermin will enhance our robust CVRM pipeline and support the acceleration of our key assets, while delivering synergies with our prioritized indications, obesity, and IBD.
- Our ambition is to complement and strengthen our existing CVRM portfolio programs, aiming to address the critical challenges of highly prevalent obesity-related comorbidities such as MASH, across moderate to severe disease stages by tapping into the potential of this FGF21 analog.

17. How does this collaboration fit into Roche's overall corporate business development strategy?

- We continue to strengthen our pipeline by bringing in external innovation focused on the therapeutic areas defined in our Pharma Strategy with the ultimate goal to deliver transformative medicines for patients.
- Following our deal with Alnylam and the acquisition of Carmot, as well as our recently signed collaboration with Zealand Pharma, this acquisition demonstrates a continuation of our strategic investment in cardiovascular and metabolic (CVRM) diseases.

18. What is the overall market opportunity you see in MASH?

- Metabolic Dysfunction-Associated Steatohepatitis (MASH) is a form of liver disease that is becoming increasingly prevalent worldwide, largely driven by the global rise in obesity and type 2 diabetes, as most (>75%) of MASH patients also live with overweight, obesity, and/or type 2 diabetes as comorbidities. Today, MASH is estimated to affect about 5—7% of the world's adult population, and based on this, it can be seen as a global metabolic health epidemic at an inflection point with the first and only approved treatment in 2024.
- In 2024, the global MASH treatment market size was estimated to be around $2.47 billion, and some experts expect this to increase to $10 to $30 billion by the 2030s.

19. Should we expect more deals in the obesity space from Roche?

- Following our previous deal with Alnylam and the acquisition of Carmot, as well as our recently signed collaboration with Zealand Pharma, this announcement underlines the continuation of our strategic investment to foster our presence in cardiovascular and metabolic (CVRM) diseases.
- The acquisition of 89bio allows us to build a competitive portfolio with an FGF21 analog that offers a differentiated mode of action with a promising safety and tolerability profile for patients with moderate to severe MASH.
- However, a high unmet need remains in CVRM, and we continue to explore new options, both through external opportunities and in-house programs to bring transformative therapy solutions to patients in need.

20. This sector requires significant development investments from Roche. Will you have to make any trade-offs with other areas of the portfolio for this?

Beyond any particular transaction, we continue to review our portfolio and optimise our excellence in R&D. We continue to allocate capital accordingly across our broad portfolio, prioritising assets and programs that have the best chance of addressing unmet patient needs, as well as accelerating those that will bring the greatest benefit to patients.

21. Who do you see as key competitors?

- We do not comment on our competitors. With the current availability of treatment options, a high unmet need still exists. We strongly believe that pegozafermin can have a significant impact in addressing that need.
- We also see opportunities for combinations with our existing assets (e.g., with our GLP1-analog) to treat obesity and its comorbidities.

22. What is your manufacturing strategy for the product, particularly in relation to the BiBo collaboration?

- We will evaluate our manufacturing strategy holistically following the closing of the transaction. Overall, our manufacturing strategy is to ensure uninterrupted Ph3 clinical supply, registration enabling qualifications, and successful registration, launch, and commercial supply by working with 89bio's CDMOs such as BTPH, BiBo, and INCOG.

89bio and Pegozafermin

23. Who is 89bio?

- Founded in 2018, 89bio is a clinical-stage biopharmaceutical company focused on the development of innovative therapies for the treatment of liver and cardio-metabolic diseases. 89bio's pegozafermin is being developed for the treatment of MASH. Pegozafermin is a specifically engineered glycoPEGylated analog of FGF21. 89bio is headquartered in San Francisco.

24. What is pegozafermin, and what is its benefit?

- 89bio's investigational asset pegozafermin is an FGF21 analog currently in Phase 3, is a protein that mimics the function of a natural hormone in the body. Through the application of glycoPEGylation technology, this molecule has been engineered to last longer in the body while addressing the underlying metabolic causes of liver and heart-related conditions, including moderate to severe MASH (F2/F3 and F4).
- The asset was initially developed by Teva Pharmaceutical Industries, but is now being developed by 89bio after Teva transferred the related intellectual property in 2018.
- Acting essentially as a metabolic regulator, 89bio's pegozafermin tackles MASH from several angles. It helps reduce liver fat, lessen inflammation, and improve liver scarring (fibrosis)—a key driver of severe MASH. It also boosts insulin sensitivity and lowers harmful fats.
- In the ENLIVEN Phase 2b trial, it showed positive results for MASH resolution and fibrosis improvement, even suggesting the potential to prevent progression to cirrhosis. So far, it has demonstrated a favourable safety and tolerability profile, which is vital for long-term treatment.

25. How does pegozafermin differentiate from other therapies in this space, specifically resmetirom?

We cannot comment on the asset profiles of our competitors. We firmly believe that pegozafermin's distinct mechanism of action, especially its impact on insulin sensitivity and potent fibroinflammatory actions, offers a promising approach for treating MASH across various disease stages and other metabolic diseases. We view it as well-positioned based on its efficacy, tolerability, and safety profile to date.

26. What is the patient population that can benefit from this asset?

- Pegozafermin is being developed to treat patients with Metabolic Dysfunction-Associated Steatohepatitis (MASH) who also have liver fibrosis. Specifically, its ongoing Phase 3 clinical trial program (ENLIGHTEN) is targeting two distinct patient populations:
    - Non-cirrhotic MASH patients with fibrosis (F2-F3): These are individuals whose MASH has progressed to cause notable scarring of the liver, but it has not yet reached cirrhosis. This group is at high risk for progressing to more severe liver disease.
    - MASH patients with compensated cirrhosis (F4): This is a more advanced patient population where the liver has significant scarring (cirrhosis) but is still able to function adequately. Treating MASH at this stage to achieve fibrosis regression is particularly challenging, and pegozafermin is notable for being one of the first FGF21 analogs to enter Phase 3 trials for this specific group.

27. What potential combinations are there for pegozafermin?

The data from 89bio's ENLIVEN study suggests there may be potential for a combination of pegozafermin with several assets, such as incretins and others. FGF21 is a foundational target and amenable to combinations with various other modes of action. We will certainly explore this further alongside other combination optionalities.

28. There is clinical data available showing pegozafermin could be used in SHTG treatment. Do you have plans to proceed with this as well?

We have a thoughtful and intentional portfolio process that seeks to ensure that we are bringing innovative and transformative therapies to the market that have a significant impact on patients' unmet medical needs. This process is driven by the data and the science. We look forward to the SHTG trial readout of topline results in Q1 2026 and would determine next steps based on the data and the differentiational potential compared to treatment alternatives.

29. How big do you estimate the total addressable market for your obesity portfolio to be? And for MASH?

- Some analysts estimate the obesity market to become as large as $100 billion annually by the 2030s, and the market linked to comorbidities could be more extensive. Thus, we firmly believe that multiple therapy options will be needed to address the growing needs worldwide.
- The total addressable market for MASH is projected to be substantial, driven by the high and rising global prevalence of the disease, particularly as it's linked to the epidemics of obesity and type 2 diabetes. In 2024, the global MASH treatment market size was estimated to be around $2.47 billion, and some experts expect this to increase to $10—30 billion by the 2030s.
- Offering a new therapy option for the treatment of moderate to severe MASH holds the potential to create significant value for healthcare systems, since MASH and MASH-related cirrhosis are seen as the main drivers for liver transplantations over the next 5—10 years.

30. Given the current entry of incretins (e.g. semaglutide approval) in the MASH space, how do you see pegozafermin differentiating from incretins, and what concerns, if any, do you have around incretins shrinking the addressable MASH patient population?

- Incretins and pegozafermin differ in their mechanism of action as incretins mainly promote weight loss by mimicking the effects of natural hormones like GLP-1 and enhance glucose control. Pegozafermin, on the other hand, is a Fibroblast Growth Factor 21 (FGF21) analog with a combined anti-inflammatory and anti-fibrotic mechanism of action and insulin sensitizer. Insulin resistance is a *sine qua non* of MASH pathogenesis, and therefore, an insulin sensitizer is critical to address this pathophysiology.
- While incretins address MASH by tackling its underlying metabolic drivers such as type 2 diabetes (T2DM) and obesity through systemic weight loss – i.e. essentially as a secondary effect and less so as a direct antifibrotic, pegozafermin focuses on treating MASH itself, especially with its fibroinflammatory effects while also directly addressing insulin resistance. Thus, pegozafermin tackles MASH from several angles: reduce liver fat, lessen inflammation, and improve liver scarring (fibrosis)—a key driver of severe MASH and poor outcomes
- The most important differentiator for pegozafermin is that lean mass is not affected by FGF21 whereas incretins will lead to more lean mass loss (can be up to 40% lean mass loss). Lean mass loss is a major issue in people with cirrhosis, and loss of lean mass directly correlates with worse outcomes; thus, we do not want more lean mass loss in those who already have sarcopenia

31. What is the expected peak sales for the asset?

While we cannot comment on exact peak sales numbers, we are convinced that pegozafermin has the potential to become a large, multi-billion commercial opportunity.

32. What kind of data is available for 89bio's pegozafermin?

Study data is available for pegozafermin, primarily from its Phase 2b ENLIVEN trial.

- Phase 2b ENLIVEN Trial

A multi-center, randomized, double-blind, placebo-controlled Phase 2b trial that evaluated pegozafermin in 219 adult patients with biopsy-confirmed non-cirrhotic MASH and F2 or F3 fibrosis. It included a 24-week main study period followed by a blinded extension phase.

Key Results (24-Week Data):

The investigational therapy demonstrated significant improvements in both primary histology endpoints, including fibrosis improvement and MASH resolution (without fibrosis worsening). It also showed significant reductions in liver fat, liver enzymes, and non-invasive markers of liver inflammation and fibrosis, alongside improvements in metabolic markers such as HbA1c, adiponectin, and lipids. The treatment was generally well-tolerated, with mostly mild to moderate gastrointestinal side effects and no clinically significant changes in vital signs, bone biomarkers, or DEXA scans. Additionally, 48-week extension data confirmed sustained benefits in liver fat, fibrosis, inflammation, and robust efficacy in F2/F3 MASH patients, subgroups on GLP-1 therapy, while maintaining a strong safety profile over the longer term.

*For more information see here the **ENLIVEN study data***

33. Are there studies ongoing for 89bio's pegozafermin?

- Yes, 89bio is currently running the Phase 3 ENLIGHTEN clinical trial program for its investigational therapy, pegozafermin, which comprises two pivotal randomized, double-blind, placebo-controlled studies using co-primary endpoints that assess MASH resolution or fibrosis improvement without worsening of the other condition.
- The ENLIGHTEN-Fibrosis trial targets non-cirrhotic MASH patients (fibrosis stages F2/F3). It aims to assess the efficacy and safety of pegozafermin (30mg weekly or 44mg biweekly) versus placebo, focusing on assessing the endpoints fibrosis improvement and MASH resolution at week 52, with approximately 1,050 adult patients (age 18-80) globally. First topline results are expected in H1 2027.
- The ENLIGHTEN-Cirrhosis trial focuses on MASH patients with compensated cirrhosis (F4 fibrosis), evaluating pegozafermin in this advanced group with an expected enrollment of 760 adult patients (18-80). Notably, pegozafermin is the first FGF21 analog to reach Phase 3 trials for MASH patients with compensated cirrhosis, underscoring its potential in addressing urgent needs in liver disease. First results are expected in 2028.

34. When do you foresee launching this asset?

The asset is expected to launch towards the end of the decade.

Portfolio

35. How does this acquisition complement your existing portfolio? Aren't you going too broad in your portfolio with so many different assets?

- Acquiring 89bio, with its pegozafermin currently in Phase 3, offers a strong strategic fit with our CVRM therapeutic area and overall Pharma strategy. Pegozafermin offers a distinct mechanism of action that not only holds the potential for best-in-disease efficacy and tolerability to address the critical challenges of highly prevalent obesity-related comorbidities such as MASH. It also unlocks opportunities for future combination development, creating synergies with Roche's CVRM portfolio and our prioritized indications, obesity and IBD.
- Looking at our portfolio, it is set up for broad optionality, recognizing the heterogeneity of the patient population while catering to the diverse therapy needs. It is designed to offer holistic solutions centered around currently unmet patient needs.

36. Do you believe the SC or oral administration will prevail in the obesity market in the years to come?

Injectables are currently the standard route of application and are expected to remain a significant part of the treatment regimen going forward. In the long term, we believe that both forms of administration (subcutaneous and oral) have benefits to drive outcomes for specific populations, depending on efficacy and different patients' needs and their preferences.

37. Which other clinical stage assets in your CVRM portfolio are you considering for combination therapies?

In general, we see opportunities for combinations to further improve weight loss or drive other functional benefits, which could further positively impact patients' lives. Roche has multiple existing assets in its portfolio, which could be considered for combination development:

- The combination of CT-388 and petrelintide potentially offers best-in-disease efficacy for weight loss, weight management, glycemic control, and end-organ protection while providing good tolerability. Both petrelintide and CT-388 are currently in Phase 2 studies, and we will need to review the results of these studies before we can share very specific details and timelines for a Phase 2 combo trial initiation.
- CT-388 + GYM-329 could help to preserve muscle mass, which is lost in patients on incretin therapy.
- A Phase II trial investigating GYM329 in combination with an approved incretin in patients living with obesity, without T2D, has started this year.
- Based on available clinical data, we see the potential for pegozafermin to be a best-in-disease FGF21 monotherapy while also expanding into combination therapies with e.g. GLP-1 analogs, thus creating synergies with Roche's CVRM portfolio.

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IMPORTANT ADDITIONAL INFORMATION AND WHERE TO FIND IT

The tender offer for the outstanding shares of common stock of 89bio has not yet commenced. This announcement is for informational purposes only and does not constitute a recommendation, an offer to purchase or a solicitation of an offer to sell 89bio's securities. The solicitation and offer to purchase 89bio's common stock will only be made pursuant to an offer to purchase and related tender offer materials. At the time the tender offer is commenced, Roche Holdings, Inc. ("Roche") and its acquisition subsidiary, a wholly owned subsidiary of Roche, will file a Tender Offer Statement on Schedule TO with the Securities and Exchange Commission (the "SEC") and thereafter, 89bio will file a Solicitation/Recommendation Statement on Schedule 14d-9 with the SEC with respect to the tender offer. The tender offer materials (including the Offer to Purchase, a related Letter of Transmittal and other tender offer documents) and the Solicitation/Recommendation Statement on Schedule 14d-9 will contain important information.

INVESTORS AND STOCKHOLDERS ARE URGED TO READ THESE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT, AS MAY BE AMENDED FROM TIME TO TIME, CAREFULLY WHEN THEY BECOME AVAILABLE PRIOR TO MAKING ANY DECISIONS WITH RESPECT TO WHETHER TO TENDER THEIR SHARES IN THE TENDER OFFER BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION, INCLUDING THE TERMS AND CONDITIONS OF THE TENDER OFFER.

The tender offer materials and the Solicitation/Recommendation Statement will be filed with the SEC, and investors and stockholders may obtain a free copy of these materials (when available) and other documents filed by Roche and 89bio with the SEC at the website maintained by the SEC at www.sec.gov. Free copies of the offer to purchase, the related letter of transmittal and certain other offering documents will be made available by Roche and when available may be obtained by directing a request to the Information Agent for the tender offer which will be named in the Tender Offer Statement on Schedule TO. Investors and stockholders may also obtain free copies of the documents filed with the SEC by 89bio on the investor relations page of 89bio's internet website at https://ir.89bio.com.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This communication may include statements that are not statements of historical fact, or "forward-looking statements," within the meaning of the federal securities laws, including with respect to Roche's proposed acquisition of 89bio. Any express or implied statements that do not relate to historical or current facts or matters are forward-looking statements. These statements are generally identified by words or phrases such as "believe", "anticipate", "expect", "intend", "plan", "will", "may", "should", "estimate", "predict", "project," "strategy," "potential", "continue" or the negative of such terms or other similar expressions. Such statements include, but are not limited to, the ability of Roche and 89bio to complete the transactions contemplated by the merger agreement, including each party's ability to satisfy the conditions to the consummation of the offer contemplated thereby and the other conditions set forth in the merger agreement, statements about the expected timetable for completing the transaction, the parties' beliefs and expectations and statements about the benefits sought to be achieved in Roche's proposed acquisition of 89bio, the potential effects of the acquisition on both Roche and 89bio and the possibility of any termination of the merger agreement. These statements are based upon the current beliefs and expectations of Roche and 89bio's management and are subject to significant risks and uncertainties. There can be no guarantees that the conditions to the closing of the proposed transaction will be satisfied on the expected timetable if at all. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements, and you should not place undue reliance on these statements.

Risks and uncertainties include, but are not limited to, uncertainties as to the timing of the offer and the subsequent merger; uncertainties as to how many of 89bio's stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the offer and the merger contemplated by the merger agreement may not be satisfied or waived, including that a governmental entity may prohibit, delay or refuse to grant approval for the consummation of the tender offer or the subsequent merger; the ability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing; the effects of disruption from the transactions contemplated by the merger agreement and the impact of the announcement and pendency of the transactions on 89bio's business; the possibility that the milestone payments related to the contingent value right will never be achieved and that no milestone payment may be made; and the risk of legal proceedings being brought in relation to the transactions and the outcome of such proceedings, including the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability. The foregoing factors should be read in conjunction with the risks and cautionary statements discussed or identified in 89bio's public filings with the SEC, including the "Risk Factors" section of 89bio's Annual Report on Form 10-K for the year ended December 31, 2024 and subsequent Quarterly Reports on Form 10-Q, Form 8-K and in other filings 89bio makes with the SEC from time to time, as well as the tender offer materials to be filed by Roche and its acquisition subsidiary and the Solicitation/Recommendation Statement to be filed by 89bio, in each case as amended by any subsequent filings made with the SEC.

Neither Roche nor 89bio undertakes any obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law.