

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 13, 2025

Metagenomi, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41949
(Commission File Number)

81-3909017
(IRS Employer
Identification No.)

**5959 Horton Street
7th Floor
Emeryville, California**
(Address of Principal Executive Offices)

94608
(Zip Code)

Registrant's Telephone Number, Including Area Code: (510) 871-4880

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	MGX	Nasdaq Global Select Market

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

Emerging growth company

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

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 13, 2025, the board of directors (the “Board”) of Metagenomi, Inc. (the “Company”) approved an increase in the size of the Board from five directors to six directors and, upon recommendation of the Nominating and Corporate Governance Committee, appointed Eric Bjerkholt to serve as a director of the Board, each effective as of January 27, 2025 (the “Effective Date”). Mr. Bjerkholt will serve as a Class II director with a term expiring at the Company’s 2026 Annual Meeting of Stockholders or until his successor is duly elected and qualified or until his earlier resignation, death or removal. As of the Effective Date, Mr. Bjerkholt will serve as a member of each of the Audit Committee of the Board and Compensation Committee of the Board.

Mr. Bjerkholt, 65, has served as the Chief Financial Officer of Mirum Pharmaceuticals, Inc., a biopharmaceutical company developing treatments for orphan and rare diseases, since September 2023. Prior to that, Mr. Bjerkholt worked at Chinook Therapeutics, Inc., a biopharmaceutical company focused on kidney diseases, from November 2020 to August 2023 where he served as Chief Financial Officer overseeing financial reporting, planning and budgeting, internal controls, investor relations, facilities, and information technology functions. In August 2023, Chinook Therapeutics was acquired by Novartis AG. Before Chinook Therapeutics, Inc., he served as the Chief Financial Officer of Aimmune Therapeutics, Inc., a biotechnology company developing treatments for food allergies, from April 2017 to November 2020, at which time, Aimmune was acquired by Nestle Health Science US Holdings, Inc. Prior to Aimmune Therapeutics, Mr. Bjerkholt spent 13 years at Sunesis Pharmaceuticals, Inc. from 2004 until 2017, where in addition to his role as Chief Financial Officer, Mr. Bjerkholt served in various capacities, including Executive Vice President of Corporate Development and Finance, Corporate Secretary and Chief Compliance Officer. Previously, Mr. Bjerkholt held senior executive finance roles at IntraBiotics Pharmaceuticals, Inc., LifeSpring Nutrition, Inc. and Age Wave, LLC and spent seven years in healthcare investment banking at J.P. Morgan & Company, Inc. He is currently a member of the board of directors of Surrozen, Inc., a publicly traded biotechnology company, and a member of the board of directors of Cerus Corporation, a publicly traded biotechnology company. Mr. Bjerkholt previously served as a member of the board of directors and Chair of the audit committee of CalciMedica, Inc., a publicly traded biotechnology company. Mr. Bjerkholt holds a Cand. Oecon degree in economics from the University of Oslo and an M.B.A. from Harvard Business School.

The Board has determined that Mr. Bjerkholt is independent under the applicable Nasdaq listing rules. There are no arrangements or understandings between Mr. Bjerkholt and any other person pursuant to which he was selected as a director. There are no related party transactions between the Company and Mr. Bjerkholt (or any of his immediate family members) requiring disclosure under Item 404(a) of Regulation S-K. Mr. Bjerkholt does not have any family relationships with any of the Company’s directors or executive officers.

In accordance with the Company’s non-employee director compensation policy (the “Director Compensation Policy”), the Company will pay Mr. Bjerkholt annual retainers for his service on the Board and committees thereof. In addition, on February 3, 2025 (the “Grant Date”), pursuant to the Director Compensation Policy, Mr. Bjerkholt will be granted a one-time non-statutory stock option to purchase 42,000 shares of the Company’s common stock, par value \$0.0001 per share (“Common Stock”), under the Company’s 2024 Stock Option and Incentive Plan, at an exercise price per share equal to the closing price per share of the Company’s Common Stock on the Grant Date (the “Initial Option Grant”). The Initial Option Grant shall vest over three years, with 33% vesting on the first anniversary of the Grant Date and the remaining 67% vesting in 24 equal monthly installments thereafter, subject to continued service on the Board.

Item 7.01 Regulation FD Disclosure.

On January 16, 2025, the Company updated information reflected in a slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the updated presentation in conjunction with its participation at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, CA and in subsequent meetings with analysts, investors and others, from time to time.

The information contained in this Item 7.01 (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.

Description

99.1

[Investor Presentation of Metagenomi, Inc., dated January 16, 2025*](#)

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Cover Page Interactive Data File (embedded within the Inline XBRL document)

*Furnished herewith

SIGNATURES

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

Metagenomi, Inc.

Date: January 16, 2025

By: /s/ Brian C. Thomas
Brian C. Thomas, Ph.D.
Chief Executive Officer



Unlocking 4 Billion Years of Microbial Evolution to Create Curative Genetic Medicines

43rd Annual J.P. Morgan Healthcare Conference

Nasdaq: MGX

January 2025

Forward Looking Statements

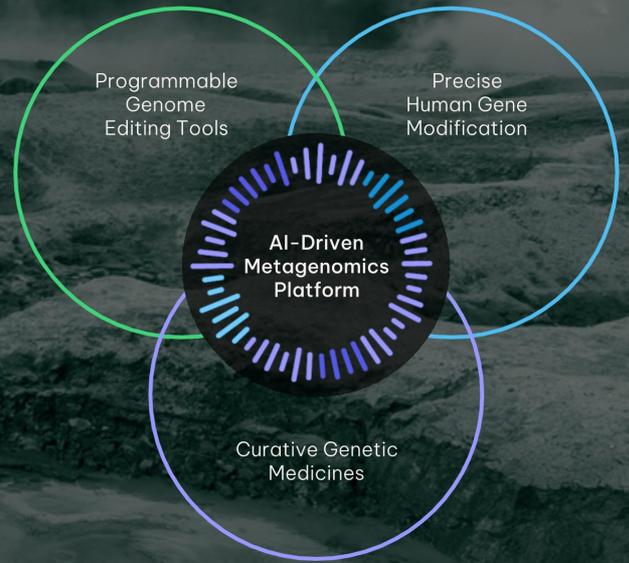
This presentation includes forward-looking statements, including forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this presentation are forward looking statements, including statements regarding our cash runway, strategy and plans, industry environment, potential growth opportunities, and the therapeutic potential of our programs. The words “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “design,” “expect,” “could,” “plan,” “potential,” “predict,” “seek,” “should,” “would,” or the negative version of these words and similar expressions are intended to identify forward-looking statements.

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, strategy, short and long term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including but not limited to, our ability to develop and advance our programs and product candidates, our ability to maintain and establish collaborations or strategic partnerships, our regulatory approvals and filings, and other risks, uncertainties and assumptions identified in our filings with the Securities and Exchange Commission (the “SEC”), including our most recent Form 10-K and Form 10-Q filed with the SEC, and any subsequent filings with the SEC.

Moreover, we operate in a very competitive and rapidly changing environment and it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking statements and circumstances discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, except as required by law, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this presentation to conform these statements to actual results or to changes in our expectations, unless required by law.

Our Vision:

Harness the power of our metagenomics platform to create curative genetic medicines for patients



The metagenomics platform is the foundation of our gene editing toolbox



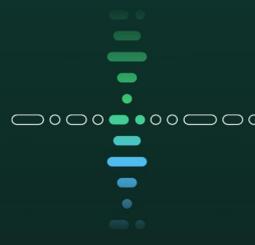
Proprietary Sampling

Exploring diverse microbe-rich ecosystems to extract DNA from environmental samples



AI-powered Screening

Leveraging AI, ancestral reconstruction, proprietary algorithms, robotics, and automation to reveal novel cellular machinery



Engineering & Optimization

Designing and optimizing novel gene editing tools to set new standards in targetability, precision, efficiency, and scope of editing capabilities



Complete Genome Editing Capabilities

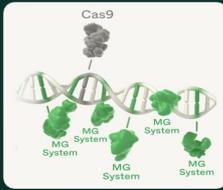
Building a proprietary toolbox capable of correcting any genetic mutation anywhere in the human genome

Our proprietary toolbox enables precise edits of the human genome



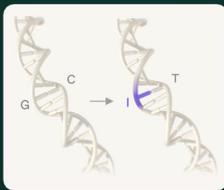
MG Tool

Nuclease



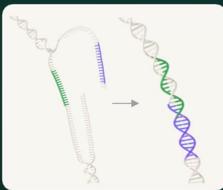
Proprietary library of highly precise and efficient nucleases, including ultra-small systems (SMARTs), provides programmable chassis for other gene editing tools

Base Editors



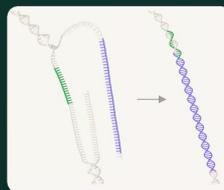
Programmable chassis with additional effector enzymes to cause single nucleotide changes

RIGS: Replacement



RNA-mediated integration systems (RIGS) use programmable chassis with additional reverse transcriptase for edits encoded in RNA templates

RIGS: Integration



RIGS with expanded RNA template for site-specific integration of genes

CAST



CRISPR-associated transposases (CAST) use DNA templates to allow for site-specific gene integration

Genomic Correction

Knockdown, knock-in, exon skipping

Single nucleotide changes

1-100 base pair replacement, insertion, or deletion

>100 base pair integrations

>10,000 base pair integrations



Broad pipeline built on our gene editing platform



Editing Platform	Delivery	Indication / Editing Target	Discovery	Lead Optimization	IND-Enabling	Clinical	Partner	
LIVER <i>Knock-in</i> <i>Knockdown</i>	LNP + AAV	Hemophilia A / ALB						
		Undisclosed secreted protein diseases						
	LNP	Transthyretin Amyloidosis / TTR					IONIS	
		Refractory Hypertension / AGT					IONIS	
		Undisclosed cardiovascular disease					IONIS	
		Undisclosed cardiovascular disease					IONIS	
Other Program: Primary Hyperoxaluria Type 1 / HAO1								
Small gene corrections	LNP	Alpha 1 Antitrypsin Deficiency / SERPINA1						
Large gene insertion	LNP	Wilson's Disease / ATP7B						
CELL THERAPY <i>Multiplex editing</i>	Ex vivo	Solid tumor indications / TCR T Cells					affini	
		Multiplex editing: Undisclosed cell therapy applications						
NEURO-MUSCULAR <i>Ultra small systems</i>	LNP / AAV	Programs in Research: Familial ALS, Duchenne Muscular Dystrophy, Charcot Marie Tooth Disease						
		LUNG, KIDNEY Large gene insertion		Programs in Research: Undisclosed renal diseases, Cystic Fibrosis				

2024 milestones and key publications

Hemophilia A Program

- ✓ Declared MGX-001, wholly-owned Development Candidate (DC)
- ✓ Factor VIII activity sustained in NHP study for more than 16 months presented at ASH¹
- ✓ Initial regulatory engagement with FDA
- ✓ GxP Manufacturing activities initiated

Secreted Protein Deficiencies

- ✓ In vivo proof-of-concept (PoC) achieved with initial targets

Cardiometabolic Programs

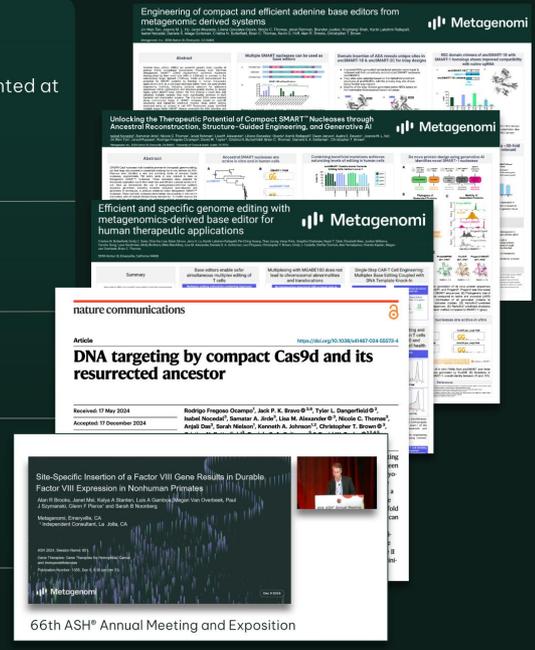
- ✓ All four Wave 1 collaboration targets in lead optimization
- ✓ In vivo rodent PoC achieved for all targets

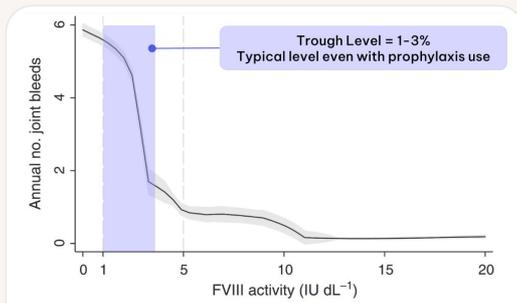
Other Therapeutic Programs / Technology Development

- ✓ AI-enabled nuclease and base editor development presented at CSHL²
- ✓ Multiplex base editing data presented at ESGCT³
- ✓ Ultra-small nucleases published in *Nature Communications*⁴

1. American Society of Hematology (ASH) 66th Annual Meeting and Exposition, San Diego, December 2024
 2. 10th meeting on Genome Engineering: CRISPR Frontiers at Cold Spring Harbor Laboratory, New York, August 2024
 3. European Society of Gene and Cell Therapy (ESGCT) 31st Annual Congress in Rome, Italy, October 2024
 4. <https://doi.org/10.1038/s41467-024-55573-4>

All posters and publications can be found at <https://metagenomi.co/news/posters-publications>





Adapted from Den Uijl et al. 2011. Haemophilia. Vol. 17, pp. 849-853



International Hemophilia Training Center, 2024. Hemophilia Joint Bleeds. <https://www.ihc.org/hemophilia-joint-bleeds>. Accessed 23 Aug. 2024.

Disease Background

- Most common X-linked inherited bleeding disorder; vast majority of patients are male
- Caused by large variety of mutations in the Factor VIII (FVIII) gene leading to loss of functional FVIII protein
- Intracranial bleeding is of greatest concern as this can lead to major morbidity and mortality
- Bleeding into joints leads to cumulative joint damage and is a major cause of morbidity
- Diagnosis typically occurs in infancy due to exaggerated bleeding in response to minor injury or routine medical procedures

Prevalence

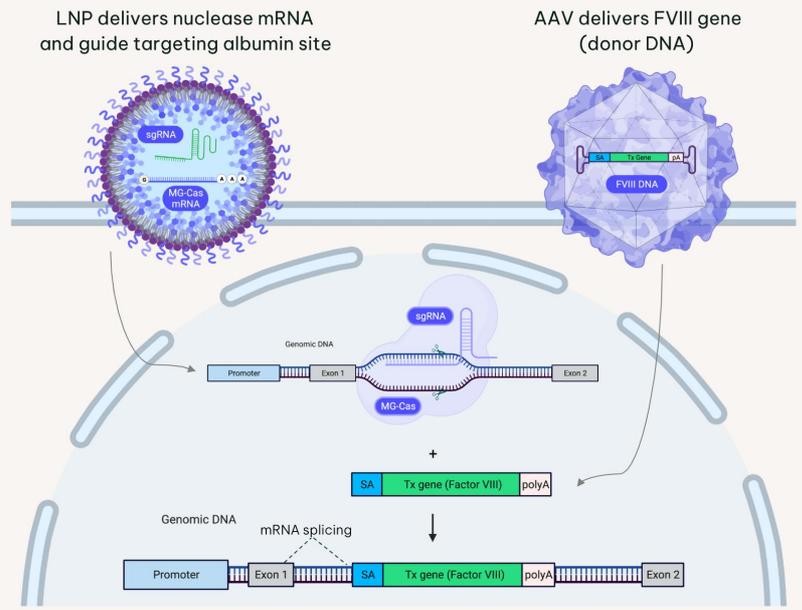
- Up to **26,500** patients in US¹
- More than **500,000** patients globally²

1. Soucie, J.M., et al. 2020. Haemophilia. Vol. 26, no. 3, pp. 487-493.
 2. Stonebraker, J. S., et al. 2010. Haemophilia. Vol. 16, pp. 20-32.



Genome editing approach

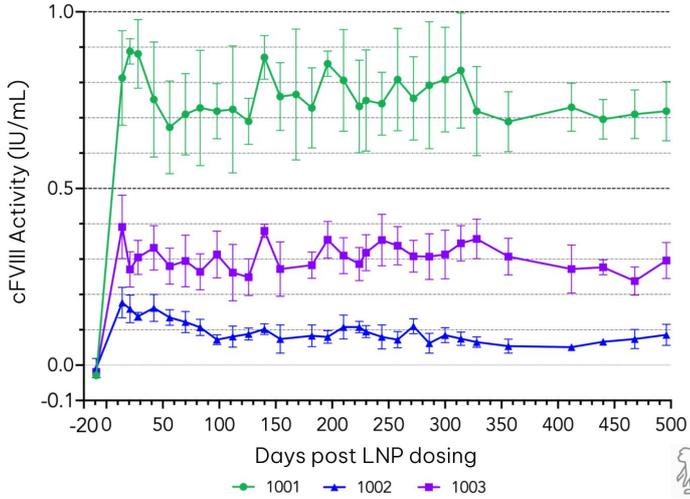
- MG nuclease creates efficient and specific cut at safe harbor locus in albumin gene
- Factor VIII donor DNA is inserted at cut site
- Strength of albumin promoter provides high level of FVIII expression even at low integration rates
- Mechanistically different from AAV gene therapy
 - Integrated vs episomal FVIII gene
 - Native promoter vs exogenous promoter





Durable FVIII activity achieved in non-human primates (NHP)

Wild-type FVIII activity levels sustained for 16.5 months
(Data cutoff: 11-13-24)



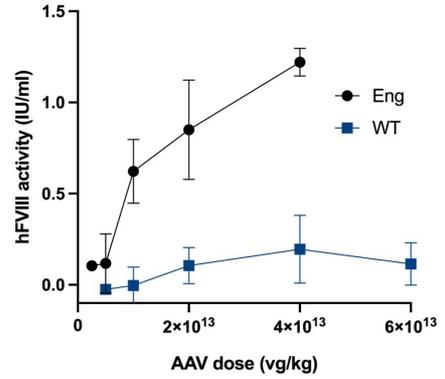
Factor VIII activity values are the mean and standard deviation of at least 3 independent assay runs with each sample run in at least duplicate in each assay

The day 168 plasma sample for 1002 and 1003 were excluded because they appear to have been switched (mis-labelled) at the CRO



Mouse dose dependent FVIII activity

Bioengineered FVIII construct used in MGX-001 has higher activity than wild-type FVIII



Data source: "Site-Specific Insertion of Factor VIII Gene Results in Durable Factor VIII Expression in Nonhuman Primates," oral presentation at American Society of Hematology (ASH) 66th Annual Meeting and Exposition, San Diego, December 2024





Potential OT site discovery

Three orthogonal methods:

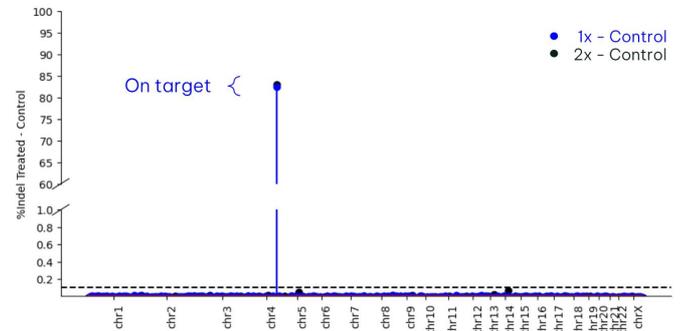
- In silico prediction
- In cell assay
- Biochemical (in vitro) assay

⇒ 481 potential sites

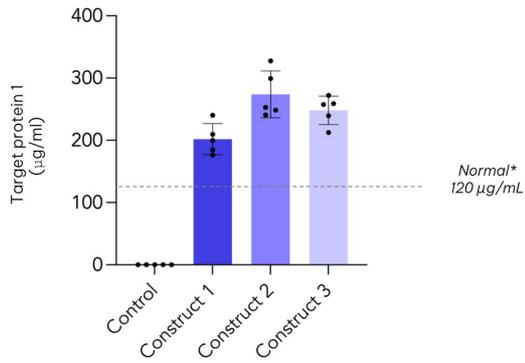
Interrogate all 481 sites for editing

- PHH edited at a dose that results in saturating editing and a dose 2x higher
- Perform sensitive amplicon sequencing

No off-target editing observed



Target protein in mice can achieve normal circulating levels with multiple construct designs

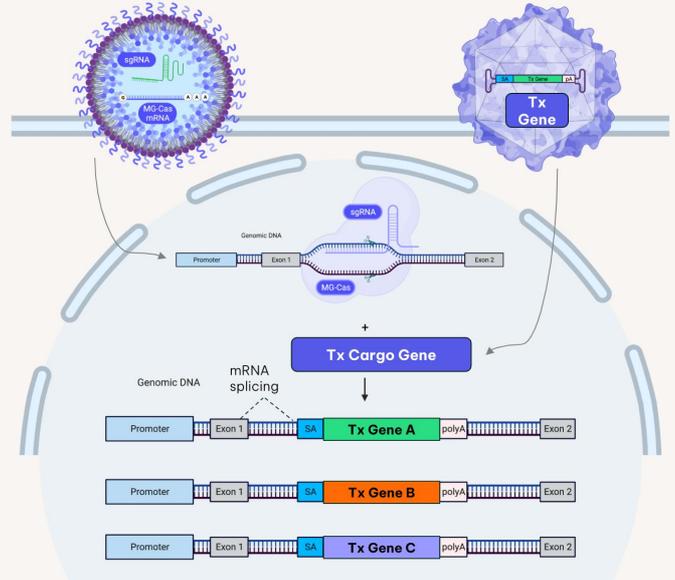


- >200% of normal human protein expression achieved in mouse plasma
- Insertion assessed with multiple DNA template constructs
- LNP and AAV dose titration can be used to fine tune therapeutic window



LNP delivers nuclease mRNA and guide targeting albumin site

AAV delivers donor DNA

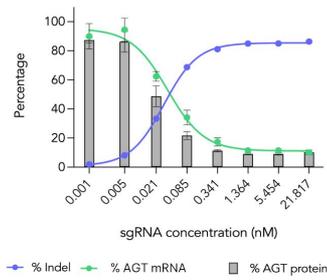


Refractory hypertension is characterized as uncontrolled hypertension despite the use of five or more drugs and is a significant risk for major cardiovascular events

Prevalence: 900K adults with refractory hypertension in the US

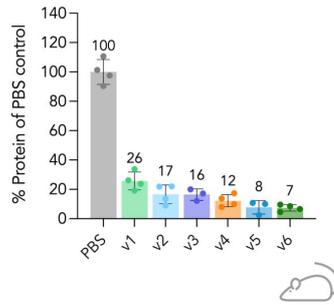
Dose dependent editing, mRNA and protein knockdown in primary human hepatocytes

>85% editing, 90% mRNA and protein knockdown



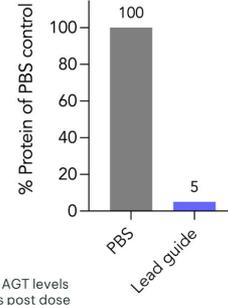
mRNA, gRNA, and LNP were optimized to increase potency

Human AGT transgenic mice
LNP dosed at 0.1 mg/kg



95% protein knockdown in spontaneous hypertensive rats

Evaluation of blood pressure reduction planned in longer term study



Plasma AGT levels
2 weeks post dose



1. Acelajado, M. C., et al. 2019. Treatment... Circulation Research, 124(7), 1061-1070
2. Yoon, M. et al. 2022. "Prevalence..." Hypertension Research, vol. 45, no. 8, pp. 1353-1362

Anticipated milestones allow advancement towards the clinic



	2025	2026	
Hemophilia A Program	<ul style="list-style-type: none">• Complete ongoing NHP durability study• Conduct Pre-IND and ex-US regulatory meetings	<ul style="list-style-type: none">• IND / CTA filings	
Secreted Protein Deficiencies	<ul style="list-style-type: none">• Disclose lead indication for secreted protein deficiency platform• Achieve NHP PoC	<ul style="list-style-type: none">• Nominate DC	
Cardiometabolic Programs	<ul style="list-style-type: none">• Nominate 1-2 DCs• Disclose indications for remaining Wave 1 targets	<ul style="list-style-type: none">• Initiate IND enabling activities• Additional DCs for Wave 1 targets	
Other Therapeutic Programs / Technology Development	<ul style="list-style-type: none">• Continue to advance early-stage pipeline for multiple future IND filings		

IND = Investigational New Drug
CTA = Clinical Trial Authorization

Metagenomi: Pipeline advancing, positioned for success

Driving towards clinic with wholly-owned MGX-001 in hemophilia A

Leveraging MGX-001 to establish secreted protein deficiencies platform

Advancing cardiometabolic programs with Ionis

Progressing additional wholly owned therapeutic candidates

Realizing the potential of our AI-enabled gene editing capabilities

Well capitalized with cash runway into 2027



Harnessing the power of our metagenomics platform to create curative genetic medicines for patients