

**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): September 28, 2022

PepGen Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41374
(Commission File Number)

85-3819886
(IRS Employer
Identification No.)

245 Main Street
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02142
(Zip Code)

Registrant's Telephone Number, Including Area Code: 781 797-0979

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, par value \$0.0001 per share	PEPG	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 7.01 Regulation FD Disclosure.

On September 28, 2022, PepGen Inc. issued a press release titled “PepGen Reports Positive Data from Phase 1 Trial of PGN-EDO51 for the Treatment of Duchenne Muscular Dystrophy” and will hold a videoconference to present related information. Copies of the press release and presentation slides are furnished with this report as Exhibits 99.1 and 99.2, respectively.

The information contained in Item 7.01 of this Current Report on Form 8-K and Exhibits 99.1 and 99.2 attached hereto are intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press release issued by PepGen Inc. on September 28, 2022
99.2	September 28, 2022, presentation titled "PepGen Reports Positive Data from Phase 1 Trial of PGN-EDO51 for the Treatment of Duchenne Muscular Dystrophy"
104	Cover page interactive data file (embedded within the Inline XBRL document)

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 thereunto duly authorized.

PepGen Inc.

Date: September 28, 2022

By: /s/ Noel Donnelly
Noel Donnelly, Chief Financial Officer



PepGen Reports Positive Data from Phase 1 Trial of PGN-EDO51 for the Treatment of Duchenne Muscular Dystrophy

- PGN-EDO51 exhibited the highest levels of oligonucleotide delivery and exon skipping in a clinical study following a single dose when compared to publicly available clinical data for other exon 51 skipping approaches -

- PGN-EDO51 was generally well-tolerated -

- PepGen plans to initiate a Phase 2a multiple ascending dose (MAD) clinical trial in Duchenne muscular dystrophy (DMD) patients in 1H 2023 -

- Data supports the potential of PepGen's Enhanced Delivery Oligonucleotide (EDO) platform in neuromuscular diseases -

- Company to host conference call today at 8:00 a.m. ET to discuss these results -

Boston, September 28, 2022 – PepGen Inc. (Nasdaq: PEPG), a clinical-stage biotechnology company advancing the next generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases, today announced results from its completed Phase 1 healthy normal volunteer (HNV) trial of PGN-EDO51, the company's lead product candidate for the treatment of DMD patients whose mutations are amenable to an exon 51 skipping approach.

PepGen's Phase 1 HNV trial of PGN-EDO51 was a single ascending dose (SAD) clinical trial evaluating the safety and tolerability of PGN-EDO51 in 32 healthy adult males. Oligonucleotide tissue concentration and exon skipping were also assessed. Following intravenous administration of PGN-EDO51, safety data were evaluated by a Safety Review Committee prior to progressing to the next dose level. Volunteers were dosed with either 1, 5, 10 or 15 mg/kg of PGN-EDO51 or placebo. The trial met its primary endpoint assessing the safety profile of PGN-EDO51 at pharmacologically relevant doses.

"We are thrilled to announce that we have observed very high levels of oligonucleotide delivery and exon skipping in muscle in our Phase 1 HNV trial. The EDO technology performed above our expectations," said James McArthur, Ph.D., President and CEO of PepGen. "In biopsies taken from biceps, PGN-EDO51 exhibited mean exon 51 skipping levels of 1.4% following a single dose of 10 mg/kg, and mean levels of 2.0% following a single dose of 15 mg/kg. Based on cross-trial comparisons with publicly available data, we believe that these results are unprecedented and reflect the highest level of DMD exon 51 skipping observed in a clinical trial following a single dose. With the very encouraging outcome of this trial, PepGen

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plans to initiate a Phase 2a multiple ascending dose clinical trial in DMD patients in the first half of 2023. We extend our heartfelt appreciation to the participants in our Phase 1 HNV trial for their role in supporting our mission to develop transformative therapies for people living with DMD and other devastating neuromuscular diseases.”

Dr. McArthur added: “We are particularly pleased with the high levels of exon skipping observed for PGN-EDO51 at 28 days. Exon skipping was higher on Day 28 than at Day 10, which we believe, in conjunction with our tissue concentration data, suggests both sustained drug exposure and pharmacodynamic effect. Furthermore, we believe that these results could signal the potential for the accumulation of exon 51 skipped transcript and dystrophin protein in muscle tissue with repeated doses of PGN-EDO51 in people living with DMD.”

Safety and Tolerability Data

The trial met its primary endpoint providing evidence that PGN-EDO51 was generally well tolerated at pharmacologically relevant doses.

- All participants completed the trial; there were no discontinuations.
- The majority of treatment-emergent adverse events (TEAEs) were assessed as mild and resolved without any intervention. At 10 mg/kg, there were only Grade 1 (mild) adverse events (AEs).
- At 15 mg/kg, there were mild, transient, reversible changes in kidney biomarkers that resolved without intervention in all but one HNV who received IV hydration. This event was recorded as a non-life-threatening serious adverse event (SAE).
- Transient mild (Grade 1) to moderate (Grade 2) hypomagnesemia was observed in two participants at the 15 mg/kg dose and did not require any intervention.
- Serum cystatin C, the recommended biomarker to assess renal function in DMD, showed minimal change at the highest dose.

Oligonucleotide Tissue Concentration and Exon Skipping Results

A dose dependent increase in PGN-EDO51 tissue concentration and exon skipping was observed in biceps.

- Oligonucleotide Tissue Concentration:
 - In the 10 mg/kg dose cohort, PGN-EDO51 exhibited mean oligonucleotide tissue concentrations of 19 nM and 11 nM in biceps biopsies taken at Day 10 (n=6) and Day 28 (n=6), respectively.
 - In the 15 mg/kg dose cohort, PGN-EDO51 exhibited mean oligonucleotide tissue concentrations of 50 nM and 50 nM in biceps biopsies taken at Day 10 (n=5) and Day 28 (n=6), respectively.
- Exon skipping:
 - In the 10 mg/kg dose cohort, PGN-EDO51 exhibited mean exon skipping of 1.1% and 1.4% in biceps biopsies taken at Day 10 (n=6) and Day 28 (n=6), respectively.

- o In the 15 mg/kg dose cohort, PGN-EDO51 exhibited mean exon skipping of 1.4% and 2.0% in biceps biopsies taken at Day 10 (n=5) and Day 28 (n=6), respectively.

PepGen believes that these data could indicate the potential for clinically meaningful accumulation of exon 51-skipped transcripts and dystrophin in tissue with repeated doses of PGN-EDO51.

PepGen plans to present the full results from the Phase 1 HNV trial of PGN-EDO51 at an upcoming medical meeting, and the company remains on track to initiate a planned Phase 2a MAD trial evaluating PGN-EDO51 in DMD patients in the first half of 2023.

Implications for PepGen's Myotonic Dystrophy Type 1 (DM1) program and EDO pipeline

We believe that these data also support the potential of PGN-EDODM1, PepGen's lead product candidate for the treatment of DM1, and our pipeline of EDO therapeutic candidates. The tissue concentrations observed in the Phase 1 HNV trial of PGN-EDO51 were similar to those seen in a single-dose study of PGN-EDODM1 conducted in HSA^{LR} mice, a murine model of DM1, at pharmacologically active dose levels. These tissue concentrations of PGN-EDODM1 resulted in significant correction of mis-splicing and myotonia in this mouse model of disease. Dr McArthur said, "We are encouraged by these results, which we believe support the potential of PGN-EDODM1 to treat the root cause of DM1 and drive meaningful clinical outcomes for individuals living with this disease. In addition, we are committed to the DMD community, with EDO candidates for patients amenable to an exon 53, 45 and 44 approach currently in development. We believe that these results provide robust support for the potential of these candidates to change the course of disease for those living with DMD."

Conference Call

PepGen will host a corresponding conference call and a live webcast at 8:00 a.m. ET on September 28, 2022, to discuss the topline results from its Phase 1 HNV trial of PGN-EDO51. Individuals interested in listening to the conference call by webcast may do so by registering via the webcast link in the investor relations section of the company's website at: www.pepgen.com.

About PGN-EDO51

PGN-EDO51, PepGen's lead clinical candidate for the treatment of Duchenne muscular dystrophy (DMD), utilizes the company's proprietary Enhanced Delivery Oligonucleotide (EDO) technology to deliver a therapeutic oligonucleotide that is designed to target the root cause of this devastating disease. PGN-EDO51 is designed to skip exon 51 of the dystrophin transcript, an established therapeutic target for approximately 13% of DMD patients, thereby aiming to restore the open reading frame and enabling the production of a truncated, yet functional dystrophin protein. In preclinical studies, PepGen observed that treatment of non-human primates with PGN-EDO51 resulted in greater levels of exon-skipping when compared in head-to-head studies against a molecule that we believe is structurally equivalent to the most clinically-advanced peptide-conjugated oligonucleotide therapeutic candidate, which could translate to higher levels of dystrophin production in patients. PGN-EDO51 also exhibited the highest level

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of exon 51 skipping in primate skeletal muscles, including diaphragm, reported for any approved therapeutic or known development candidate, based on cross-trial comparisons of publicly available data with preclinical PGN-EDO51 data.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is an X-linked recessive muscle-wasting disease that predominantly affects males. This debilitating disease is caused by genetic mutations in the gene encoding dystrophin, a protein critical for healthy muscle function, and is one of the most prevalent rare genetic diseases, with an incidence rate of approximately one in every 3,500 to 5,000 male births. DMD is characterized by progressive muscle weakness, which leads to patients losing the ability to walk, a loss of upper body function, cardiac issues and difficulties breathing. DMD is invariably fatal by young adulthood. Despite significant advances in treatments for this devastating disease, current therapies are limited by poor delivery to muscle tissue and have yet to establish meaningful clinical benefit for DMD patients.

About Myotonic Dystrophy Type 1

DM1 is a monogenic, autosomal dominant, progressive disorder that primarily affects skeletal, cardiac and smooth muscles as well as the CNS, resulting in significant physical, cognitive and behavioral impairments and disability. The burden of disease is significant, and many patients have a shortened lifespan. DM1 is caused by an abnormal trinucleotide repeat expansion in a region of the *DMPK* gene, with an estimated prevalence of approximately 1 in 8,000. However, under- and misdiagnosis is believed to be widespread, and genetic screening studies for *DMPK* triplet repeats have suggested that this rate may be as high as 1 in 2,100 people. There are currently no approved therapies for the treatment of DM1.

About PepGen

PepGen Inc. is a clinical-stage biotechnology company advancing the next-generation of oligonucleotide therapies with the goal of transforming the treatment of severe neuromuscular and neurological diseases. PepGen's Enhanced Delivery Oligonucleotide (EDO) platform is founded on over a decade of research and development and leverages cell-penetrating peptides to improve the uptake and activity of conjugated oligonucleotide therapeutics. Using these EDO peptides, we are generating a pipeline of oligonucleotide therapeutic candidates that are engineered to target the root cause of serious diseases. For more information, visit www.pepgen.com or follow PepGen on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking

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statements include, without limitation, statements about our clinical and preclinical programs, product candidates, including their planned development and therapeutic potential, plans for future development and clinical trials in our programs, including the planned initiation of a Phase 2a MAD trial of PGN-EDO51 in DMD patients, achievement of milestones, and corporate and clinical/preclinical strategies.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to that we may fail to successfully complete preclinical studies and clinical trials of our product candidates or to obtain regulatory approval for marketing of such products; initial clinical trial results for one or more of our product candidates may not be predictive of future trial results for such candidates; our product candidates may not be safe and effective; there may be delays in regulatory clearance or changes in regulatory framework that are out of our control; we may not be able to nominate new drug candidates within the estimated timeframes; our estimation of addressable markets of our product candidates may be inaccurate; we may need additional funding before the end of our expected cash runway and may fail to timely raise such additional required funding; more efficient competitors or more effective competing treatments may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to attract and retain key employees and qualified personnel; earlier-stage trial results may not be predictive of later stage trial outcomes; and we are dependent on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen's programs and operations are described in its most recent quarterly report on Form 10-Q on file with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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PEPGEN REPORTS POSITIVE DATA FROM PHASE 1 TRIAL OF PGN-EDO51 FOR THE TREATMENT OF DUCHENNE MUSCULAR DYSTROPHY

James McArthur, Ph.D.
Chief Executive Officer

SEPTEMBER 28, 2022



DISCLAIMERS

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements about our clinical and preclinical programs, product candidates, including their planned development and therapeutic potential, plans for future development and clinical trials in our programs, including the planned initiation of a Phase 2a MAD trial of PGN-ED051 in DMD patients, achievement of milestones, and corporate and clinical/preclinical strategies.

Any forward-looking statements in this presentation are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to that we may fail to successfully complete preclinical studies and clinical trials of our product candidates or to obtain regulatory approval for marketing of such products; initial clinical trial results for one or more of our product candidates may not be predictive of future trial results for such candidates; our product candidates may not be safe and effective; there may be delays in regulatory clearance or changes in regulatory framework that are out of our control; we may not be able to nominate new drug candidates within the estimated timeframes; our estimation of addressable markets of our product candidates may be inaccurate; we may need additional funding before the end of our expected cash runway and may fail to timely raise such additional required funding; more efficient competitors or more effective competing treatments may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to attract and retain key employees and qualified personnel; earlier-stage trial results may not be predictive of later stage trial outcomes; and we are dependent on third parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning PepGen's programs and operations are described in its most recent quarterly report on Form 10-Q on file with the SEC. PepGen explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

POSITIVE DATA FROM PGN-EDO51 PH1 SINGLE ASCENDING DOSE TRIAL

PGN-EDO51 Ph1 HNV trial overview

- A **double-blind, placebo-controlled single ascending dose trial** evaluating the safety and tolerability of PGN-EDO51 in 32 healthy adult males; tissue concentration and exon skipping were also assessed
- Subjects were randomized to **1, 5, 10 or 15 mg/kg doses** of PGN-EDO51 or placebo
- Following a **single IV administration** of PGN-EDO51, safety data were evaluated by a Safety Review Committee (SRC) prior to dose escalation

Trial results

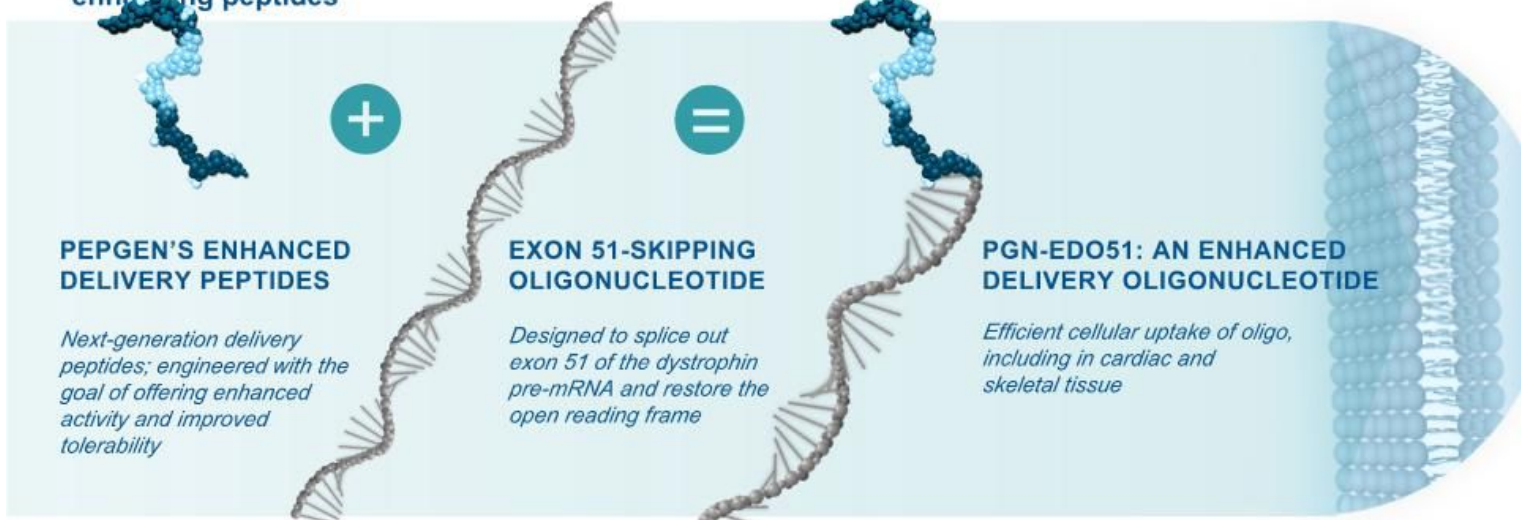
- PGN-EDO51 was **generally well-tolerated at the doses assessed**, and was **more potent than anticipated**
- We observed the **highest level of oligonucleotide delivery and exon 51 skipping in human muscle following a single dose***
- **Accumulation of exon 51-skipped transcript** was observed from day 10 to day 28, suggesting the potential for transcript and dystrophin accumulation in future repeat dose patient trials
- The **oligonucleotide tissue concentrations observed in this trial were similar to those seen in PGN-EDODM1 preclinical studies at pharmacologically active dose levels**, supporting the clinical potential of PGN-EDODM1



*Comparative statements are based on cross-trial comparisons with publicly-available data for other exon skipping approaches that have been assessed following a single dose.

PGN-EDO51 LEVERAGES PEPGEN'S ENHANCED DELIVERY OLIGONUCLEOTIDE (EDO) TECHNOLOGY

PGN-EDO51 for the treatment of Duchenne muscular dystrophy (DMD) is a well-characterized investigational exon 51-skipping oligonucleotide conjugated to one of our proprietary delivery-enhancing peptides



PEPGEN'S ENHANCED DELIVERY PEPTIDES

Next-generation delivery peptides; engineered with the goal of offering enhanced activity and improved tolerability

EXON 51-SKIPPING OLIGONUCLEOTIDE

Designed to splice out exon 51 of the dystrophin pre-mRNA and restore the open reading frame

PGN-EDO51: AN ENHANCED DELIVERY OLIGONUCLEOTIDE

Efficient cellular uptake of oligo, including in cardiac and skeletal tissue



PGN-EDO51 FOR DUCHENNE MUSCULAR DYSTROPHY

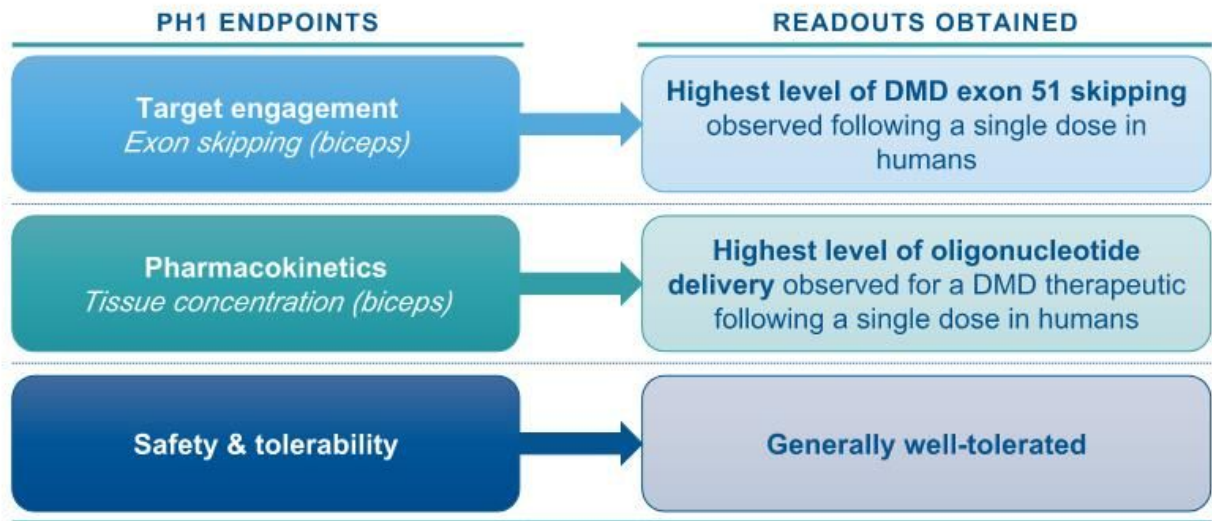
Michelle Mellion, M.D.
SVP Clinical Development

WE HAVE COMPLETED A SINGLE ASCENDING DOSE PH1 TRIAL OF PGN-EDO51 IN HEALTHY NORMAL VOLUNTEERS

PH1 HEALTHY NORMAL VOLUNTEER (HNV) TRIAL SUMMARY

Overview	<ul style="list-style-type: none">• Study population: Healthy adult males (n = 32, 3:1 PGN-EDO51:placebo)• Dosing: Single dose, i.v. administration• Placebo control• Biceps biopsies conducted on Day 10 and Day 28
Trial summary	<pre>graph LR; A["1 mg/kg n = 8"] -- SRC --> B["5 mg/kg n = 8"]; B -- SRC --> C["10 mg/kg n = 8"]; C -- SRC --> D["15 mg/kg n = 8"];</pre>

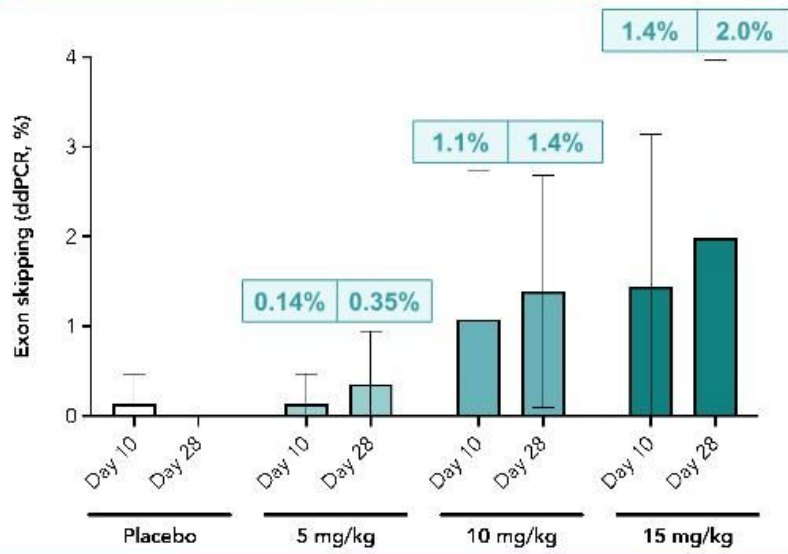
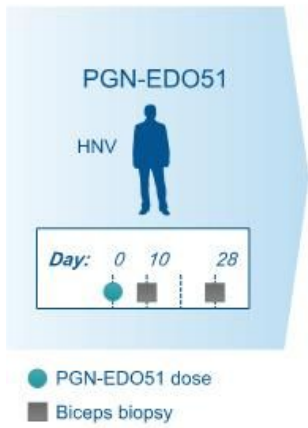
HIGHEST LEVELS OF OLIGO DELIVERY & EXON 51 SKIPPING OBSERVED, SUPPORTING FURTHER DEVELOPMENT OF PGN-EDO51



Comparative statements are based on cross-trial comparisons with publicly-available data for other exon skipping approaches that have been assessed following a single dose.

HIGHEST LEVELS OF EXON 51 SKIPPING OBSERVED IN HUMANS FOLLOWING A SINGLE DOSE

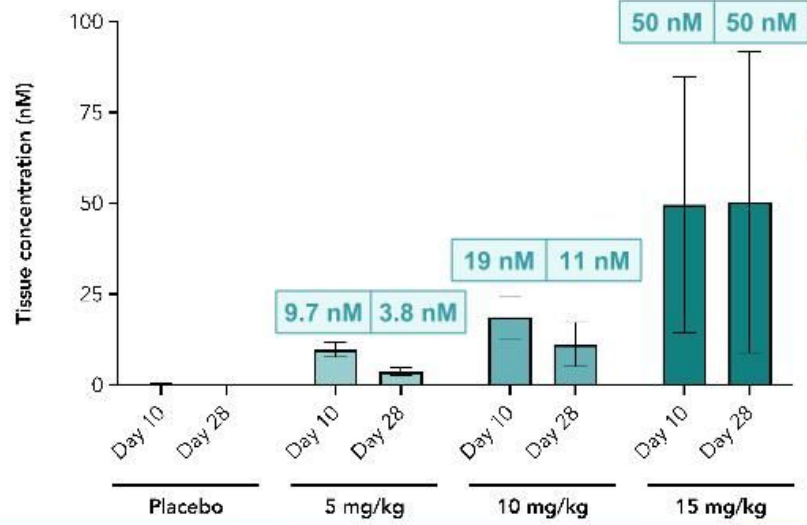
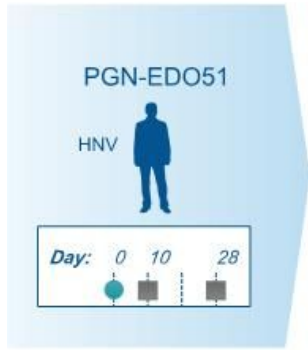
EXON SKIPPING (BICEPS)



Protocol PGN-EDO51-101: Phase 1, first in human, randomized double blind, placebo controlled single ascending dose study in healthy adult volunteers. Single dose of either PGN-EDO51 or Placebo were administered by IV infusion at doses indicated. Participants were followed for 28 day period following dose administration to evaluate safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD). Needle biopsies of biceps muscle were taken on Day 10 and Day 28. Exon skipping measured by ddPCR. Shown as mean \pm SD; n = 6 PGN-EDO51; 2 Placebo per cohort (n = 5 for D10 at 15 mg/kg). Comparative statements are based on cross-trial comparisons with publicly-available data for other exon skipping approaches that have been assessed following a single dose.

HIGH, PERSISTENT TISSUE CONCENTRATIONS OF OLIGONUCLEOTIDE WERE OBSERVED

TISSUE CONCENTRATION (BICEPS)



These results further support our belief that repeat dosing of PGN-EDO51 may lead to **accumulation of skipped transcript and dystrophin** following repeat dosing in DMD patients



Protocol PGN-EDO51-101: Phase 1, first in human, randomized double blind, placebo controlled single ascending dose study in healthy adult volunteers. Single dose of either PGN-EDO51 or Placebo were administered by IV infusion at doses indicated. Participants were followed for 28 day period following dose administration to evaluate safety, tolerability, PK, and PD. Needle biopsies of biceps muscle were taken on Day 10 and Day 28. Tissue concentration measured by ELISA. Shown as mean \pm SD; n = 6 PGN-EDO51; 2 Placebo per cohort (n = 5 for D10 at 15 mg/kg).

SAFETY & TOLERABILITY SUMMARY

- All participants completed the study; there were **no discontinuations**.
- The majority of treatment-emergent adverse events (TEAEs) were assessed as **mild and resolved without any intervention**. At 10 mg/kg there were **only Grade 1 (mild) AEs**.
- At 15 mg/kg there were **transient, reversible** changes in kidney biomarkers that **resolved in all subjects**.
- At 15 mg/kg there was one non-life threatening serious adverse event (SAE) related to changes in kidney biomarkers that were **transient and reversible**. This HNV was admitted to the hospital for less than 24 hours, received hydration and then was re-admitted to the Phase 1 unit and completed the study.
- Transient mild (Grade 1) to moderate (Grade 2) hypomagnesemia was observed in two participants at the 15 mg/kg dose and **did not require any intervention**.
- Serum cystatin C, the recommended biomarker to assess renal function in DMD, showed **minimal change at the highest dose**.



In light of higher than anticipated oligo levels and exon skipping levels in muscle observed at 5 mg/kg and 10 mg/kg, further dose escalation was not deemed necessary by sponsor. Under this Phase 1 protocol any non-life-threatening SAE was considered a dose-limiting toxicity (DLT), however study was not halted by the SRC nor put on hold by Health Canada.

MAJORITY OF TEAEs MILD AND RESOLVED WITHOUT INTERVENTION; SUPPORTS PROGRESSION TO PH2a PATIENT TRIAL

PH1 TRIAL SAFETY & TOLERABILITY SUMMARY

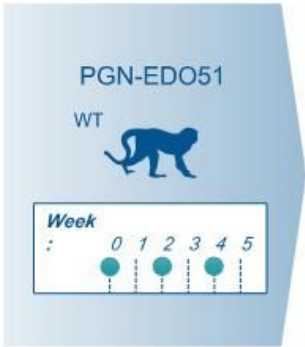
Healthy Normal Volunteers (HNV) with ≥ 1 AE, n (%)	Placebo (n=8)	Cohort A: 1 mg/kg (n=6)	Cohort B: 5 mg/kg (n=6)	Cohort C: 10mg/kg (n=6)	Cohort D: 15 mg/kg (n=6)	PGN-EDO51 Total (n=24)
Any AE	4 (50)	4 (66.7)	2 (33.3)	5 (83.3)	6 (100)	17 (70.8)
Related to study drug	1 (12.5)	2 (33.3)	0	4 (66.7)	6 (100)	12 (50)
Serious AE related to study drug	0	0	0	0	1 (16.7)	1 (4.2)
AE leading to discontinuation	0	0	0	0	0	0
AE leading to death	0	0	0	0	0	0
Number of Related TEAEs by CTCAE v5.0 grading*						
Grade 1 (Mild)	1	1	0	7	12	20
Grade 2 (Moderate)	0	1	0	0	3	4
Grade 3 (Severe)	0	0	0	0	1	1



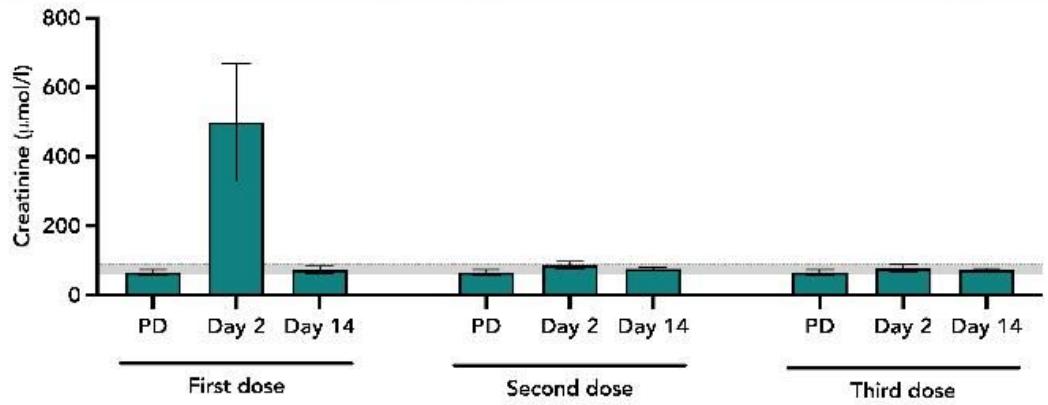
* No Grade 4 or 5 recorded; Protocol PGN-EDO51-101: Phase 1, first in human, randomized double blind, placebo controlled single ascending dose study in healthy adult volunteers. Single dose of either PGN-EDO51 or Placebo were administered by IV infusion at doses indicated. Participants were followed for 28 day period following dose administration to evaluate safety, tolerability, PK, and PD.

IN NHP REPEAT DOSE STUDY, KIDNEY BIOMARKER ELEVATIONS WERE REDUCED AFTER FIRST DOSE OF PGN-EDO51

REPEAT-DOSE SERUM CREATININE LEVELS (HIGH-DOSE COHORT)



● PPMO dose



These results support the potential tolerability of PGN-EDO51 with repeat dosing



PD = pre-dose. Protocol: PGN-EDO51 was administered to NHP by IV infusion over 30 min at a given dose level (n=3). Q2W, three doses administered, saline control. Tissues were harvested 7 days after final administration. Shown as mean \pm SD; n = 3 per group. Study was not powered for statistical significance. Grey bar shows normal range.

PEPGEN HAS COMPLETED A PH1 HNV TRIAL FOR PGN-EDO51; ON TRACK TO INITIATE DMD PATIENT CLINICAL TRIAL IN 1H23

	2022	2023	2024
Anticipated milestones	<ul style="list-style-type: none"> • 2Q: First HNV dosed in Ph1 trial • 3Q: Ph1 clinical safety, oligo delivery & exon skipping data • 4Q: Completion of Ph2a-enabling tox studies 	<ul style="list-style-type: none"> • 1H: Initiation of Ph2a DMD patient clinical trial 	<ul style="list-style-type: none"> • Safety and dystrophin data in DMD patients (Ph2a)
Overview	<ul style="list-style-type: none"> • Ph1 trial showed highest single-dose levels of exon skipping & oligo delivery • PGN-EDO51 was generally well-tolerated • We believe readouts support progression to Ph2a 	<ul style="list-style-type: none"> • Trial will assess safety and tolerability, exon skipping and dystrophin in DMD patients • Safety readouts from HNV trial anticipated to support MAD initiation at higher dose levels • Precedents suggest that exon skipping readouts will be higher in patients than in HNVs at the same dose level • Anticipate trial will be conducted in multiple geographies, including U.S. 	



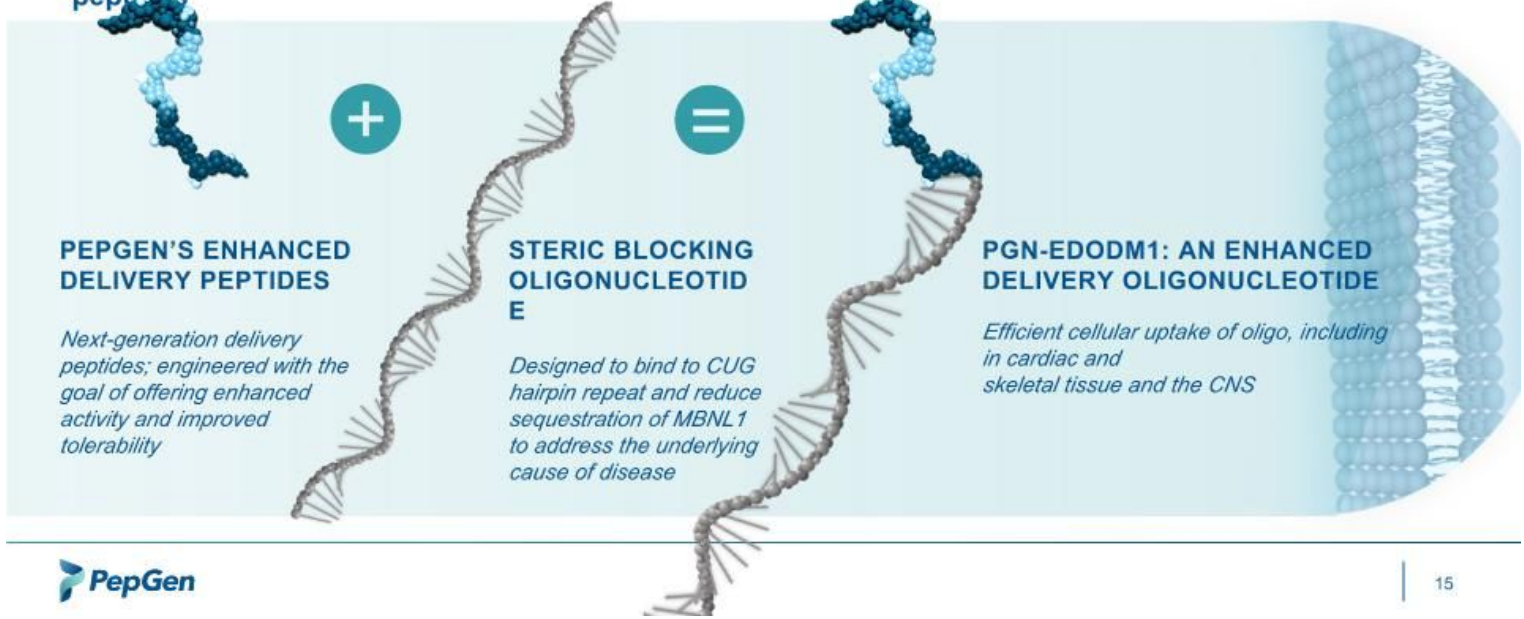
PGN-EDODM1 FOR MYOTONIC DYSTROPHY TYPE 1 (DM1)

Jaya Goyal, Ph.D.

*EVP Research & Preclinical
Development*

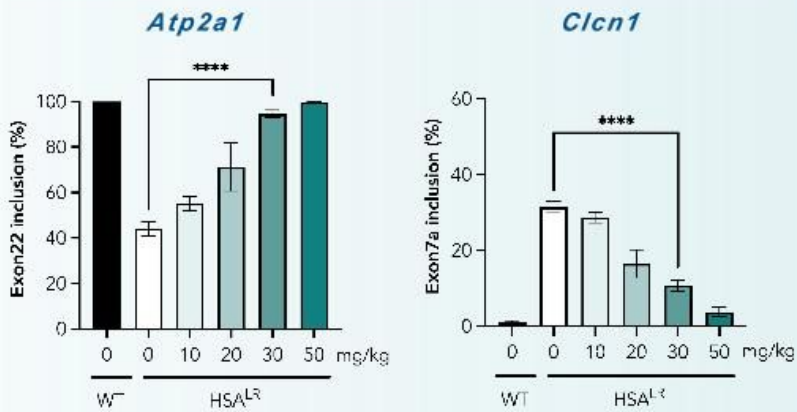
PGN-EDO51 DATA SUPPORTS THE CLINICAL POTENTIAL OF PGN-EDODM1 FOR THE TREATMENT OF MYOTONIC DYSTROPHY TYPE 1

PGN-EDODM1 for the treatment of myotonic dystrophy type 1 (DM1) is a well-characterized investigational steric blocking oligonucleotide conjugated to one of our proprietary delivery-enhancing peptides



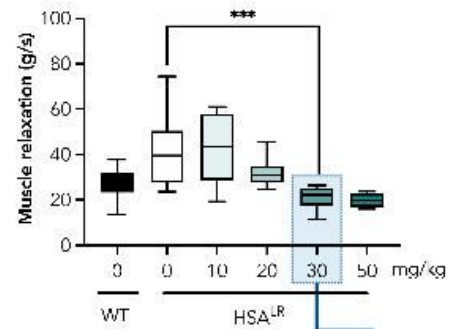
PGN-EDODM1 CORRECTED MOLECULAR AND FUNCTIONAL DM1 PHENOTYPE IN HSA^{LR} MOUSE

CORRECTION OF MIS-SPLICING



REVERSAL OF MYOTONIA

Rate of muscle relaxation



Correction of myotonia observed after a single dose of 30 mg/kg

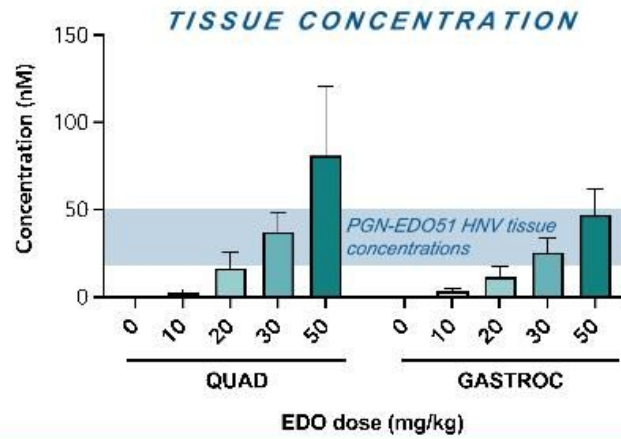


Protocol: PGN-EDODM1 was administered IV to HSA^{LR} mice at doses (mg/kg): 10, 20, 30 (n=8), 50 (n=4) against a saline control (n=16) and wild-type (WT) saline control (n=8). Myotonia assessed, tissues harvested 2 weeks post-administration. Mis-splicing data is quadriceps. Mean ± SEM or min to max. **** = p<0.0001; *** = p<0.001.

HUMAN PGN-EDO51 TISSUE CONCENTRATIONS WERE COMPARABLE TO THOSE ACHIEVED IN HSA^{LR} MOUSE MODEL

HSA^{LR} MOUSE

Robust mis-splicing correction and reversal of myotonia were observed after a **single dose of 30 mg/kg**



PGN-EDO51 Ph1

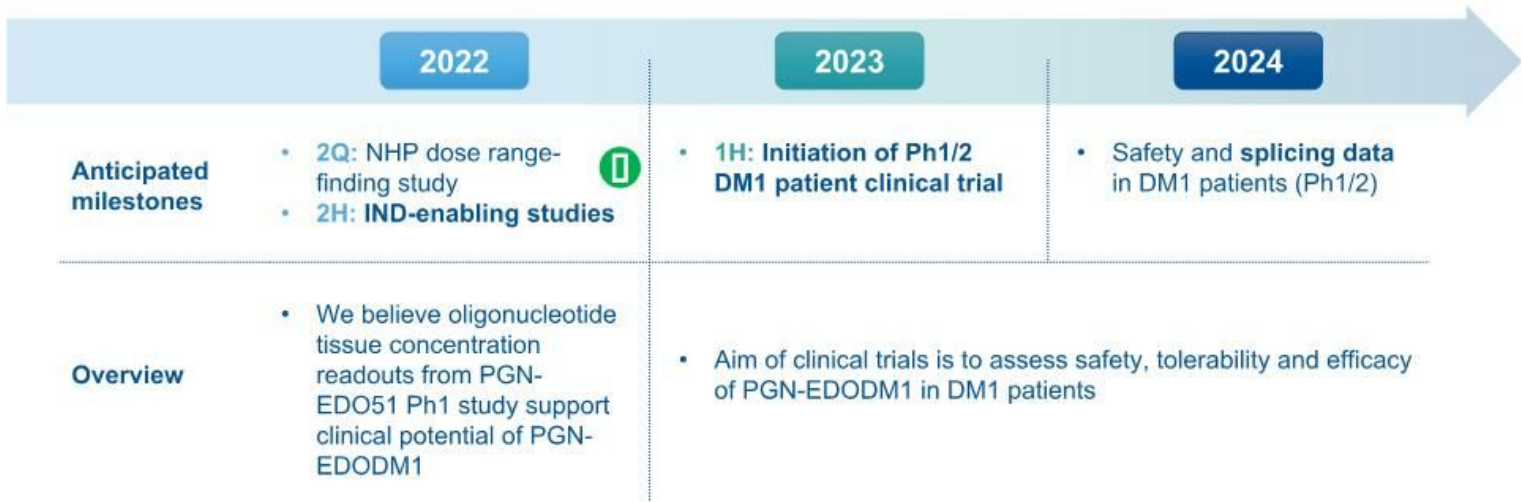
Following a single 10 or 15 mg/kg dose of PGN-EDO51 in our Ph1 HNVT trial, **tissue concentrations were similar** to those measured for PGN-EDODM1 at 30 mg/kg

We believe that PGN-EDODM1 has the potential to achieve concentrations in DM1 patients that could lead to clinically-meaningful outcomes, supporting further development of this candidate



Protocol: PGN-EDODM1 was administered IV to HSA^{LR} mice at doses (mg/kg): 10, 20, 30 (n=8), 50 (n=4) against a wild-type (WT) saline control (n=8). Tissue concentration assessed by HPLC.

PEPGEN IS ON TRACK TO INITIATE A DM1 PATIENT CLINICAL TRIAL IN 1H23



CONCLUSION

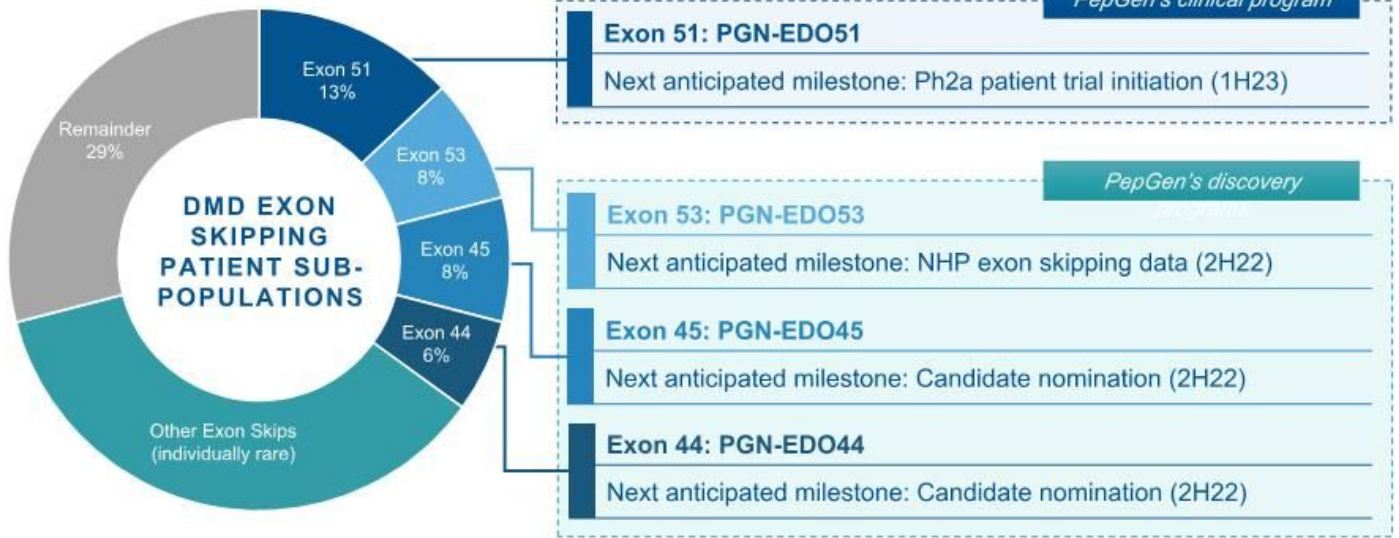
James McArthur, Ph.D.
Chief Executive Officer

SCALABLE EDO TECHNOLOGY DESIGNED TO ENABLE BROAD PORTFOLIO

PROGRAM	INDICATION TARGET	DISCOVERY	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NEXT ANTICIPATED MILESTONE
PGN-EDO51	Duchenne muscular dystrophy <i>Exon 51</i>						1H23 <i>Ph2a patient clinical trial initiation</i>
PGN-EDODM1	Myotonic dystrophy type 1 <i>DMPK</i>						1H23 <i>Ph1/2 patient clinical trial initiation</i>
PGN-EDO53	Duchenne muscular dystrophy <i>Exon 53</i>						2H22 <i>NHP exon skipping data</i>
PGN-EDO45	Duchenne muscular dystrophy <i>Exon 45</i>						2H22 <i>Candidate nomination</i>
PGN-EDO44	Duchenne muscular dystrophy <i>Exon 44</i>						2H22 <i>Candidate nomination</i>

FUTURE PIPELINE OPPORTUNITIES

Additional neuromuscular indications
Neurologic indications



THE FUTURE OF PEPGEN

2022

PGN-EDO51 (DMD exon 51) Ph1 HNV trial showed:

- **Highest level of single-dose exon skipping and oligo delivery observed in a clinical trial***
- PGN-EDO51 was generally well-tolerated

2023

Anticipate **initiation of patient clinical trials** for DMD & DM1

2024

Anticipate **clinical POC in two indications:**

- Patient dystrophin data (DMD)
- Patient splicing data (DM1)

- 5 neuromuscular disease therapies in pipeline
- Work underway to **leverage EDO platform** to expand to new tissues & new indications



* Comparative statements are based on cross-trial comparisons with publicly-available data for other exon skipping approaches that have been assessed following a single dose.

Q&A

THANK YOU
