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 12, 2026

Opus Genetics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34079**	**11-3516358**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

8 Davis Drive **Durham, NC**	**27713**
(Address of principal executive offices)	(Zip Code)

(984) 884-6030
(Registrant's telephone number, including area code)

N/A
(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	IRD	The Nasdaq Stock Market LLC

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.

As previously announced, management of Opus Genetics, Inc., a Delaware corporation (the "***Company***"), will be delivering a corporate presentation at the 44th Annual J.P. Morgan Healthcare Conference on January 15, 2026 at 8:15 a.m. Pacific Time. A live webcast of the presentation will be accessible through the investor relations section of the Company's website. The presentation is attached hereto as Exhibit 99.1 and incorporated herein by reference. The Company has also made the presentation available to investors on the "Overview" section of the Company's website at https://ir.opusgtx.com.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), nor shall such information be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing. The Company undertakes no obligation to update, supplement, or amend the materials attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	January 2026 Corporate Presentation.
104.1	Cover Page Interactive Data File (embedded within Inline XBRL document).

SIGNATURE

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.

OPUS GENETICS, INC.

Date: January 12, 2026

By: /s/ Dr. George Magrath
Name: Dr. George Magrath
Title: Chief Executive Officer

Exhibit 99.1

OPUS GENETICS®

Delivering on the Promise of Gene Therapy for Rare Inherited Retinal Diseases

January 2026

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BEST1 patie

Disclosures and Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning data from and future enrollment for our clinical trials and our pipeline of additional indications. These forward-looking statements relate to us, our business prospects and our results of operations and are subject to certain risks and uncertainties posed by many factors and events that could cause our actual business, prospects and results of operations to differ materially from those anticipated by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those described under the heading "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 and our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025, June 30, 2025 and September 30, 2025 and in our other filings with the U.S. Securities and Exchange Commission (the "SEC"). Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "aim," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. We undertake no obligation to revise any forward-looking statements in order to reflect events or circumstances that might subsequently arise. These forward-looking statements are based upon our current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: our clinical data related to gene therapies for the treatment of inherited retinal diseases is preliminary and related to a relatively small group of patients, and, as a result, data that initially appears promising may be revised, updated, or invalidated at a later data readout and/or may ultimately not be capable of duplication in additional patients; failure to successfully integrate our businesses following our acquisition of former Opus Genetics Inc. (the "Opus Acquisition") could have a material adverse effect on our business, financial condition and results of operations; the Opus Acquisition significantly expanded our product pipeline and business operations and shifted our business strategies, which may not improve the value of our common stock; our gene therapy product candidates are based on a novel technology that is difficult to develop and manufacture, which may result in delays and difficulties in obtaining regulatory approval; our planned clinical trials may face substantial delays, result in failure, or provide inconclusive or adverse results that may not satisfy the U.S. Food and Drug Administration (the "FDA") requirements to further develop our therapeutic products; delays or difficulties associated with patient enrollment in clinical trials may affect our ability to conduct and complete those clinical trials and obtain necessary regulatory approvals; changes in regulatory requirements could result in increased costs or delays in development timelines; we depend heavily on the success of our product pipeline; if we fail to find strategic partners or fail to adequately develop or commercialize our pipeline products, our business will be materially harmed; others may discover, develop, or commercialize products similar to those in our pipeline before or more successfully than we do or develop generic variants of our products even while our product patents remain active, thereby reducing our market share and potential revenue from product sales; we do not currently have any sales or marketing infrastructure in place and we have limited drug research and discovery capabilities; the future commercial success of our products could significantly depend upon several uncertain factors, including third-party reimbursement practices and the existence of competitors with similar products; product liability lawsuits against us or our suppliers or manufacturers could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop; failure to comply with health and safety laws and regulations could lead to material fines; we have not generated significant revenue from sales of any products and expect to incur losses for the foreseeable future; our future viability is difficult to assess due to our short operating history and our future need for substantial additional capital, access to which could be limited by any adverse developments that affect the financial services markets; raising additional capital may cause our stockholders to be diluted, among other adverse effects; we operate in a highly regulated industry and face many challenges adapting to sudden changes in legislative reform or the regulatory environment, which affects our pipeline stability and could impair our ability to compete in international markets; we may not receive regulatory approval to market our developed product candidates within or outside of the U.S.; with respect to any of our product candidates that receive marketing approval, we may be subject to substantial penalties if we fail to comply with applicable regulatory requirements; our potential relationships with healthcare providers and third-party payors will be subject to certain healthcare laws and regulations, which could expose us to extensive potential liabilities; we rely on third parties for material aspects of our business, such as conducting our nonclinical and clinical trials and supplying and manufacturing bulk drug substances, which exposes us to certain risks; we may be unsuccessful in entering into or maintaining licensing arrangements (such as our license agreement with Viatris, Inc.) or establishing strategic alliances on favorable terms, which could harm our business; our current focus on the cash-pay utilization for future sales of RYZUMVI may limit our ability to increase sales or achieve profitability with this product; inadequate patent protection for our product candidates may result in our competitors developing similar or identical products or technology, which would adversely affect our ability to successfully commercialize; we may be unable to obtain full protection for our intellectual property rights under U.S. or foreign laws; we may become involved in lawsuits for a variety of reasons associated with our intellectual property rights, including alleged infringement suits initiated by third parties; we are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy; as we grow, we may not be able to operate internationally or adequately develop and expand our sales, marketing, distribution, and other corporate functions, which could disrupt our operations; the market price of our common stock is expected to be volatile; our common stock may be subject to delisting from the Nasdaq Capital Market, which could adversely affect our ability to access capital markets; factors out of our control related to our securities, such as securities litigation or actions of activist stockholders, could adversely affect our business and stock price and cause us to incur significant expenses; our business could experience an adverse impact from current or proposed tariffs on imported goods we purchase; our ability to utilize our common stock to finance future capital needs, or for other purposes, is limited by our authorized shares available for issuance; and instability and operational disruptions at government agencies, such as the FDA, may adversely impact our development and commercialization plans by causing delays and requiring the use of additional, unforeseen resources to obtain regulatory approval for trials or products in our pipeline.

The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive. Readers are urged to carefully review and consider the various disclosures made by us in this report and in our other reports filed with the SEC that advise interested parties of the risks and factors that may affect our business. All forward-looking statements contained in this presentation speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

OPUS GENETICS

The Opus Opportunity: A String of Pearls Strategy

7 Targeted IRD AAV gene therapy assets

Portfolio approach produces multiple data readouts and milestones

Validated science & delivery approach

Follow-on treatments from the first approved IRD gene therapy

1st Mover advantage in multiple indications

2 of 7 assets in clinical trials: upside across additional patient populations

Streamlined timelines & capital efficiency

Cost-effective development: efficient programs with compelling economics

Rare disease regulatory advantages

Flexibility & potentially streamlined paths to approval

Revenue & partnership streams drive value

Non-dilutive & voucher funding plus partnered strategic financial asset

LCA5 — BEST1 — RHO — RDH12 — MERTK — CNGB1 — NMNAT1

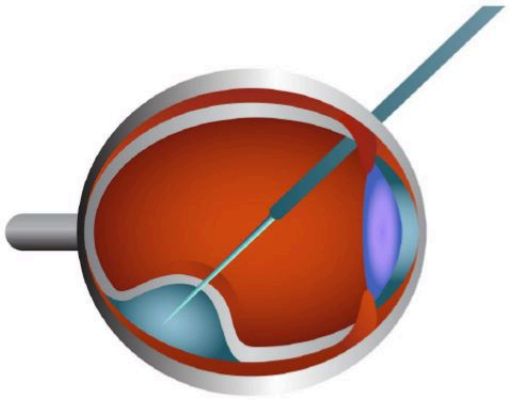
IRD, inherited retinal disease; AAV, adeno-associated virus;

Precision-Targeted, One-Time-Treatment for Rare Diseases

350+ genes known to cause IRDs

- World-class science from pioneers in gene therapy
- Structure-function biology well-characterized with measurable outcomes amenable to gene augmentation
- Rigorous selection of clinical programs
  - Grounded in natural history studies and patient registries
  - Validation using large animal models
- Single-vector technology for each indication with clear development paths; not discovery-stage
- Faster development path – able to quickly assess efficacy

Proven subretinal delivery with established safety profile and clinical precedent



Structure-Function Dissociation: The Clinical Imperative

Targeting diseases where the structure is intact

Treat the function to reverse pathology and restore or preserve vision

Retinal structure is relatively preserved even though visual function is already impaired

↓

This creates a “therapeutic window” where there are still enough viable cells for AAV gene replacement to restore function

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Pick the right patients, and choose meaningful endpoints for our clinical trials

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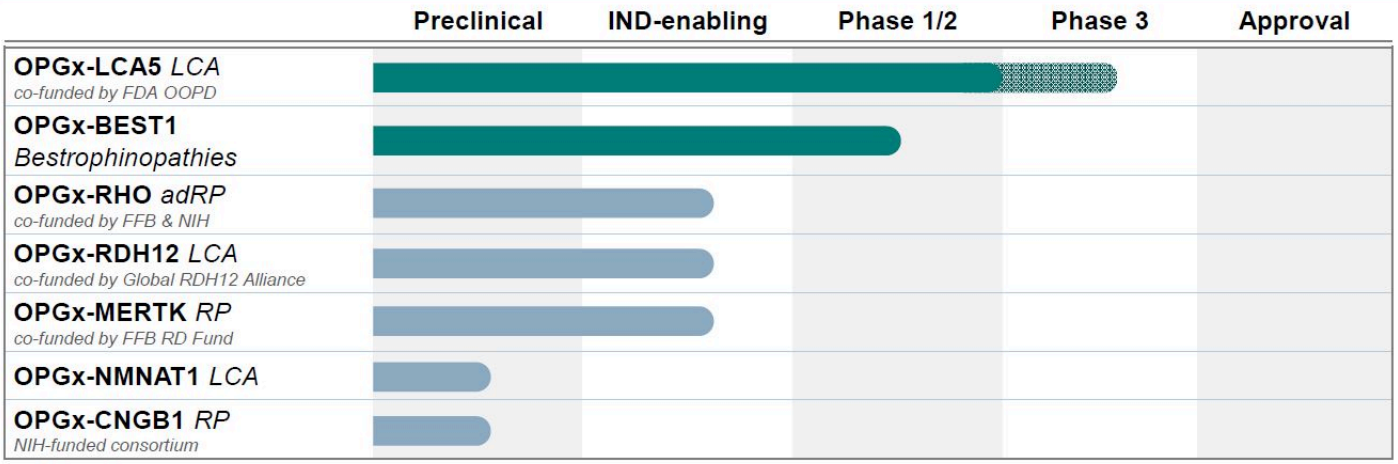
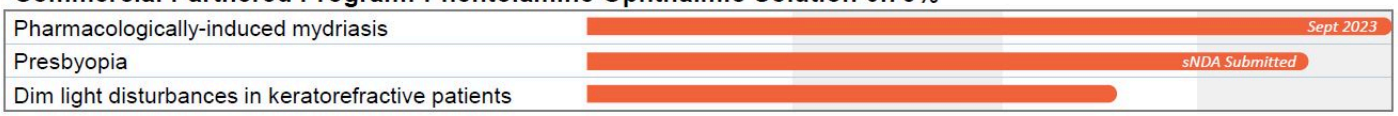
Clinical evidence for curative potential in IRDs

OPUS GENETICS

Building a Differentiated Pipeline



Commercial Partnered Program: Phentolamine Ophthalmic Solution 0.75%



Opus Genetics owns worldwide rights to all gene therapy programs.

LCA, Leber congenital amaurosis; FDA OOPD, Office of Orphan Products Development; BEST1, bestrophin 1; RHO, rhodopsin; RP, retinitis pigmentosa; FFB, Foundation Fighting Blindness; RDH12, retinol dehydrogenase 12; MERTK, MER proto-oncogene tyrosine kinase; NMNAT1, nicotinamide mononucleotide adenylyltransferase; CNGB1, cyclic nucleotide-gated channel β1;

Actively Advancing Lead Indications

OPGx-BEST1

BEST1-related mutations associated with retinal degenerative diseases

- **Phase 1/2 trial ongoing; first participant dosed in Q4 2025**
- IDMC completed pre-specified safety review of the one-month data from the sentinel participant; recommended continued enrollment without modification
- **Initial data expected in Q1 2026; 3-month results from entire Cohort 1 expected in mid-2026**
- Potential treatment for both the dominant and recessive forms of BEST1 disease
- Potentially eligible for multiple regulatory designations

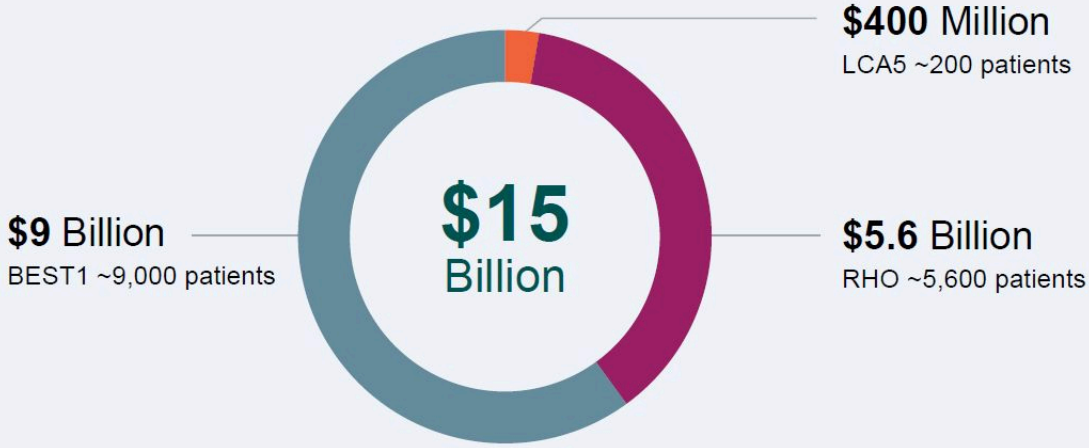
OPGx-LCA5

Early-onset, severe hereditary retinal degeneration

- Positive Phase 1/2 safety and efficacy results observed in adult and pediatric participants
- Successful Type B RMAT meeting
- **Enrollment ongoing in run-in period for planned, adaptive Phase 3 trial**
- Multiple Regulatory Designations:
  - Rare Pediatric Disease
  - Regenerative Medicine Advanced Therapy
  - Orphan Drug
- Potential eligibility for Priority Review Voucher upon BLA approval

Lead Gene Therapy Programs Target Potential $15B U.S. Market Opportunity

Efficient commercialization model leveraging small, targeted salesforce



Sources: FactSet. Data as of April 7, 2025. 2. Stone et al. *Ophthalmology*. 2017;124:1314-1331. Triangle Insights Group market research (compilation of prevalence studies), conducted August 2023.

OPGx-BEST1

Juan,
BEST1 patient

OPUS GENETICS

BEST1 Mutations are Associated with Retinal Degeneration

Prevalence

- ~9,000 patients the U.S.[1]
- Accounts for ~3.5% of all IRDs[2]

Clinical Characteristics

- Mutations in BEST1 have been associated with at least five clinically distinct retinal degenerative diseases[3]
- Bestrophinopathy is characterized by retinal lesions, with symptoms including dimness of vision, metamorphopsia (distorted vision), or scotoma (blind spot)[4]
- Mutations, depending on their impact on BEST1 function, may lead to serous retinal detachment, vitelliform lesions in the macular region, macular atrophy, and loss of central vision
- Most bestrophinopathies exhibit a slow rate of decline and central photoreceptors usually remain viable for decades, providing a wide therapeutic window

OPGx-BEST1

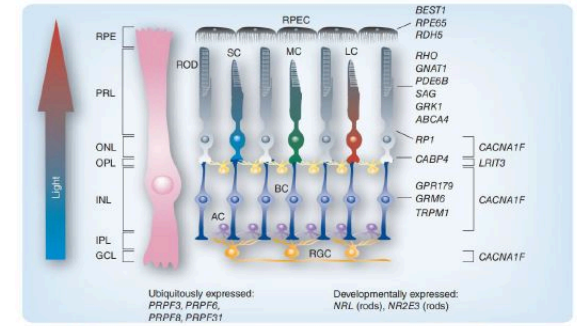
- Designed to restore retinal ion homeostasis in bestrophinopathies, ameliorating retinal structural and functional deficits
- Targeted using the AAV2 capsid employed in Luxturna and an RPE-specific promoter

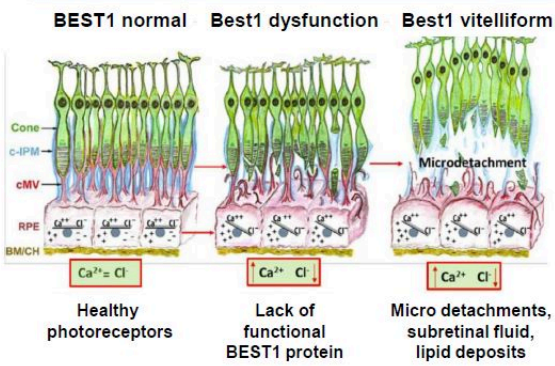
1. Triangle Insights Group market research (compilation of prevalence studies), conducted August 2023. 2. Amato A, et al. *Saudi J Ophthalmol.* 2023;37(4):287-295. 3. Johnson AA, et al. *Prog Retin Eye Res.* 2017;58:45-69. 4. Tripathy K, et al. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024.

BEST1 Disease Biology

- BEST1 gene encodes for Bestrophin-1 (basolateral RPE)
- 585 AA homo-**pentameric** transmembrane protein (5 BEST1 monomers are required for full length BEST1 channel)
- Ca2+-activated Chloride channel (CaCC)
  - Transepithelial ion transport of intracellular calcium
  - RPE cell volume
  - Homeostasis of subretinal space / IP matrix

The BEST1 protein is a pentamer that assembles as a complex of five identical monomers





IP, interphotoreceptor; RPE, retinal pigment epithelium Guziewicz KE, et al. *Prog Retin Eye Res*. 2017;58:70-88.

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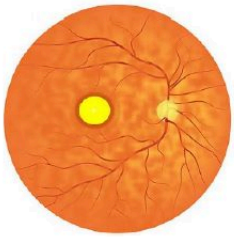
BEST1 IRDs: Clinical Staging and Pathology of Two Main Phenotypes

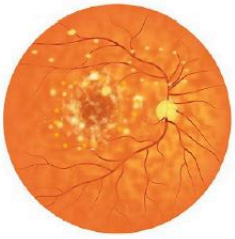
BVMD



BVMD Prevalence: 1:60,000

- Macular dystrophy similar to AMD with teen onset
- 20/60 and worse BCVA observed beginning at Stage 3 disease, leading to choroidal neovascularization, retinal detachment, chorioretinal atrophy

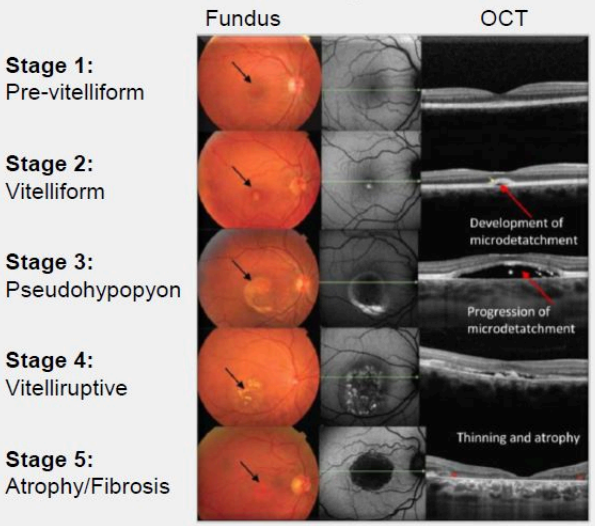
ARB



ARB prevalence: 1:1,000,000

- Severe, multifocal degeneration beginning in childhood

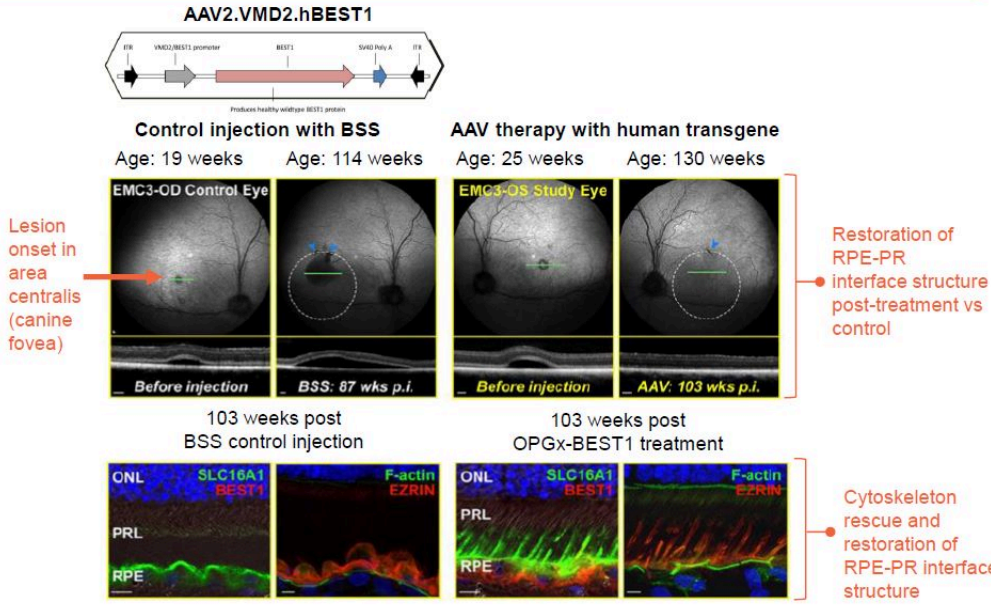
BVMD Stages



BVMD, best vitelliform macular dystrophy; ARB, autosomal recessive bestrophinopathy; AMD, age-related macular degeneration; BCVA, best-corrected visual acuity; IRD, inherited retinal disease; OCT, optical coherence tomography.

Proof of Concept of OPGx-BEST1 AAV2 in a Canine Model of ARB

- Robust restoration of RPE-photoceptor interface demonstrated in canine models of ARB using an AAV2.VMD2.hBEST1 construct
- Treated cBEST1 models exhibit reversal of lesions and retinal microdetachments, which are hallmarks BEST1 disease
- De-risked AAV2 capsid, with AAV2.VMD2 clinical precedent (MERTK) with no known safety issues
- Safety/efficacy studies in cBEST1: Regression of lesions and dose-dependent ERG improvement with favorable safety profile supporting clinical dosing
  - n=9 dogs at 16-108 weeks, low dose of 1.4E9 vg/eye and high dose of 4.5E9 vg/eye



BSS, balanced salt solution; ERG, electroretinogram; MERTK, MER proto-oncogene, tyrosine kinase; RPE, retinal pigment epithelium. Guziewicz, et al. *PNAS*. 2018;115:E2839–E2848.

OPGX-BEST1 Phase 1/2 Trial

- **Title:** Safety and Tolerability of Subretinally Injected OPGx-BEST1 in Patients With Best Vitelliform Macular Dystrophy (BVMD) or Autosomal-Recessive Bestrophinopathy (ARB) (BIRD-1)
- **Type:** Adaptive, open-label, dose-exploring, safety and tolerability study
- **Population:** adults (≥18 years old) with BVMD or ARB (n=10 total participants)
- **Treatment:** Single, subretinal injection of OPGx-BEST1 in one eye of each participant with two dosing cohorts: Cohort 1: 1.5E9 vg/eye, Cohort 2: 4.5E9 vg/eye
- **Signs of target engagement:** EOG, OCT, Microperimetry, Visual Acuity
- **Status: Enrolling**
  - First participant dosed in Q4 2025
  - Initial data expected in Q1 2026; 3-month results from entire Cohort 1 expected in mid-2026

EOG, electrooculogram; OCT, Optical Coherence Tomography

OPGx-LCA5

Alan,
LCA5 patient

OPUS GENETICS

LCA5 is an Early-Onset, Severe Hereditary Retinal Degeneration

Prevalence

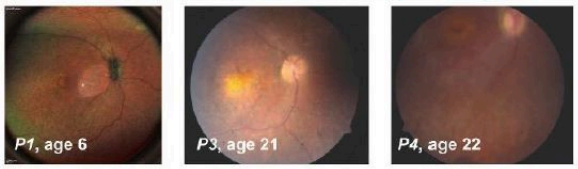
- ~200 patients in the U.S.[1,2]
- LCA5 represents ~2% of all LCA cases[3]

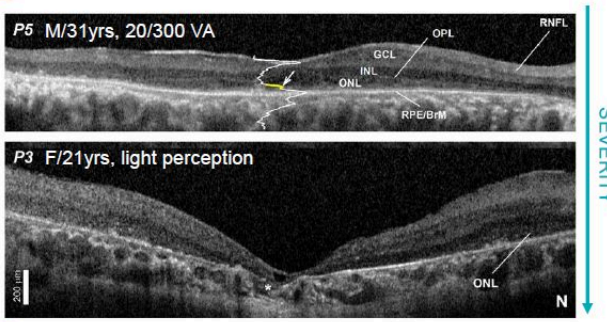
Clinical Characteristics

- Presentation in 1st year of life with nystagmus and vision loss[3,4]
- Severe and early photoreceptor loss results in severely abnormal or non-detectable visual fields[3,4]
- Visual acuity often limited to hand motions or light perception[3,4]
- Fundus photography exhibits pigmentary retinopathy with areas of RPE and photoreceptors[3]
- OCT shows spared photoreceptors (ONL) and inner/outer segments (P5) even in severe disease (P3)[3]

Structure-function dissociation creates favorable pathobiology for AAV gene replacement

LCA5 patients exhibit preserved photoreceptors in the central retina in adulthood despite disease severity and early onset





ONL, outer nuclear layer; **1.** Stone et al. *Ophthalmology*. 2017;124:1314-1331. **2.** Triangle Insights Group market research (compilation of prevalence studies), conducted August 2023. **3.** Uyhazi KE, et al. *Invest Ophthalmol Vis Sci*. 2020;61:30. **4.** Boldt K, et al. *J Clin Invest*. 2011;121(6):2169-2180.

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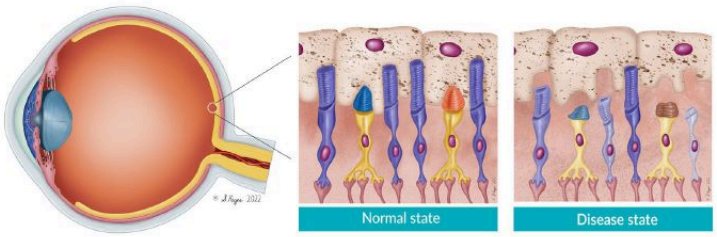
OPGx-LCA5: Designed to Restore Structure and Function in Photoreceptors

- Lebercilin is a ciliary protein critical for the function of photoreceptor inner and outer segments[1]
- In *LCA5* patients, photoreceptor function is severely impaired due to a lack of functioning lebercilin[1]
  - However, photoreceptors can survive through the third decade of life, suggestive of a broad window for therapeutic intervention[2]



- **OPGx-LCA5 is designed to address mutations in the *LCA5* gene, which encodes for the lebercilin protein**
  - Clinically derisked AAV8 vector delivers a functional *LCA5* gene directly to photoreceptor cells
  - Same promoter technology as Luxturna
  - Validated surgical delivery method via subretinal injection

1. Uyhazi KE, et al. *Invest Ophthalmol Vis Sci.* 2020;61:30. 2. Song JY, et al. *Mol Ther.* 2018;26:1581-1593.

OPGx-LCA5 Phase 1/2: Well-Tolerated with Activity on Multiple Outcome Measures

Visual Acuity

- Observed improvement in visual acuity in 5 out of 6 participants
- Initial gains as early as 1 month
- Duration of effect out to 18 months in adult participants

Full-field Stimulus Test

- Observed improvement in FST in 5 out of 6 participants
- Increased sensitivity in treated eyes and measurable photoreceptor function in all 6 participants

MLoMT

- Significant improvement observed in participants with formative vision at baseline
- Observed improvement in 2 out of 3 adult participants out to 18 months

Safety

- Well-tolerated in all 6 treated participants
- No ocular SAEs or dose-limiting toxicities
- All ocular AEs were mild, anticipated, and unrelated to study drug

FST, full-field stimulus test; MLoMT, Multi-Luminance orientation and Mobility Test; SAE, serious adverse events; AE, adverse event.

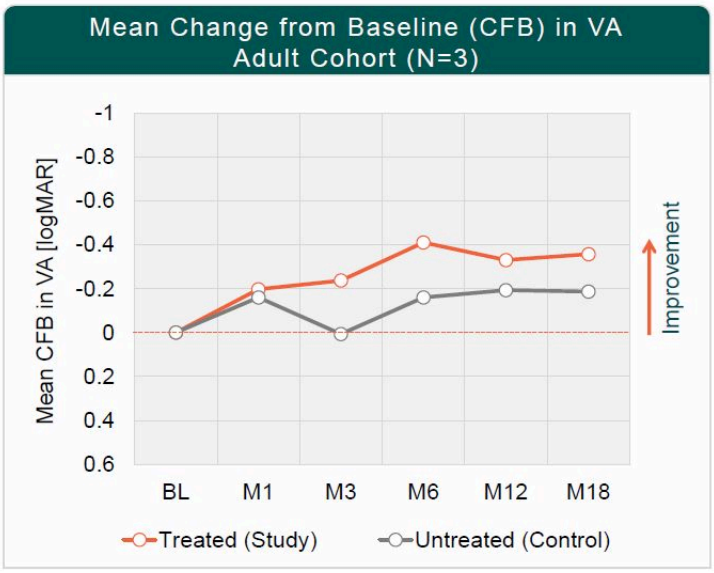
Participant Demographics in Phase 1/2 Trial

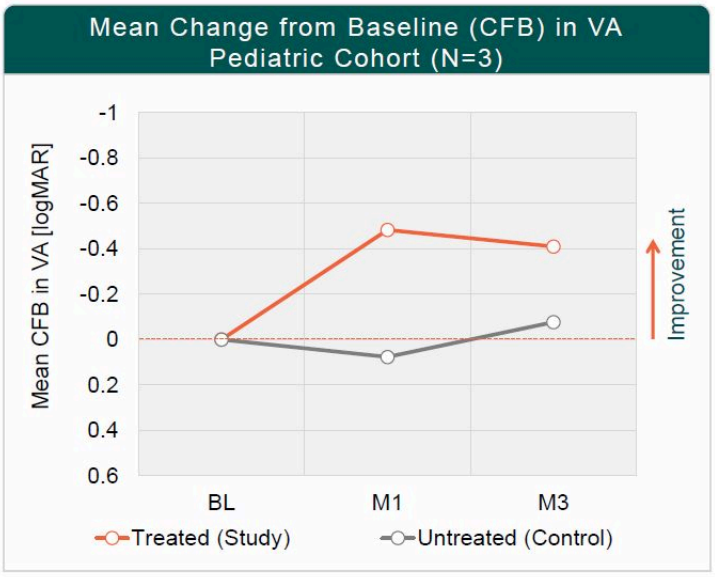
	Adult Participants			Pediatric Participants		
Participant #	**01-01**	**01-03**	**01-04**	**01-05**	**01-06**	**01-07**
Age	34	26	19	17	16	17
Gender	Female	Male	Female	Female	Male	Female
Study eye treated	Left (OS)	Left (OS)	Right (OD)	Right (OD)	Right (OD)	Right (OD)
Baseline visual acuity logMAR	1.38	2.90	0.96	2.2	0.96	2.3
Follow-up duration	18 mo.	18 mo.	18 mo.	3 mo.	3 mo.	3 mo.

The participant's eye with the worst vision was treated in all cases.

 Deemed study eye: OD, right eye; OS, left eye.

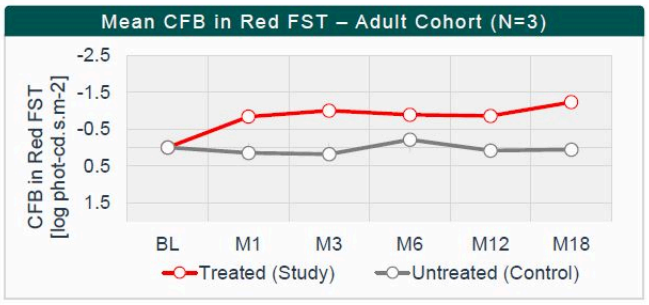
Visual Acuity Maintained in Adults Over 18 Months and Improved Over 3 Months in Pediatric Cohort

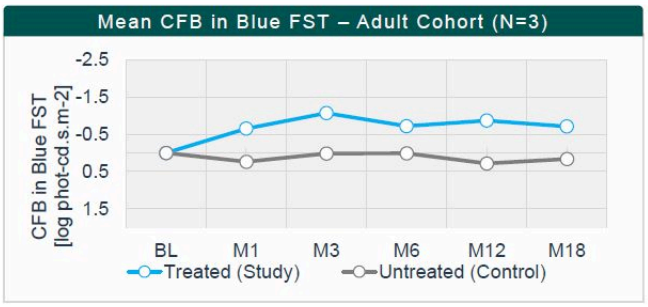


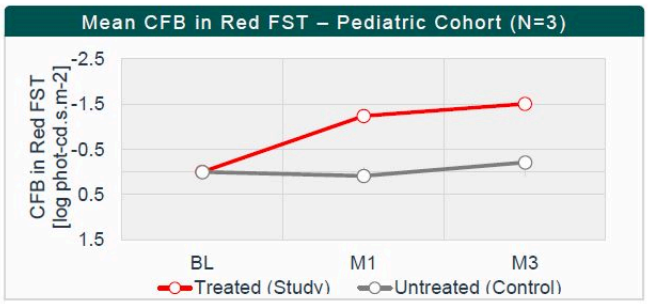


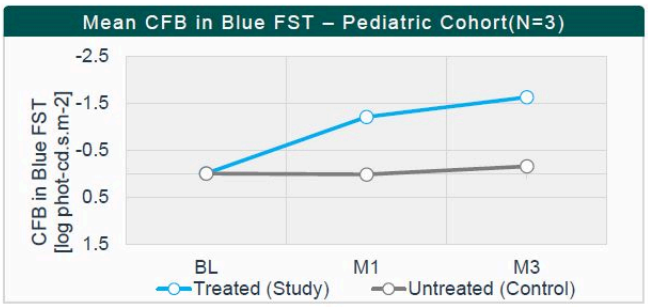
20 VA, visual acuity; BL, baseline; M, month.

Full-Field Stimulus Test (FST) Demonstrated Durable Vision Improvement



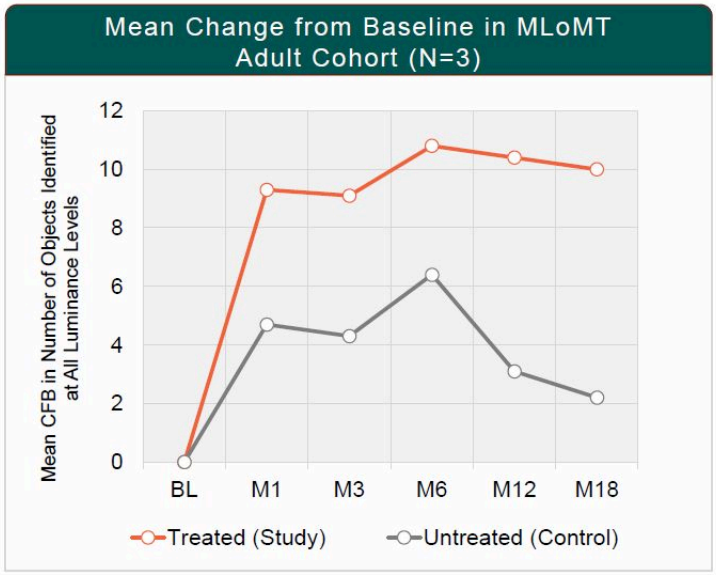


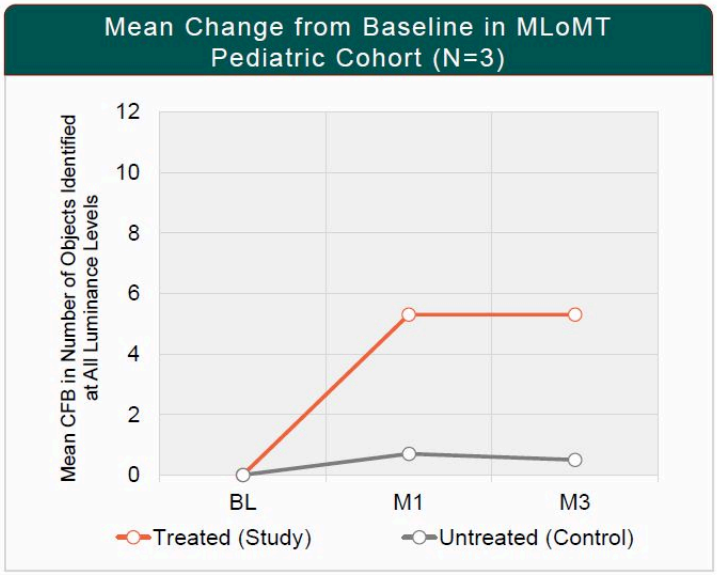




FST - Measures the cone or photoreceptor sensitivity in the eye to different wavelengths of light; BL, baseline; CFB, change from baseline; M, month.

Treated Eyes Identified More Objects on the Virtual Reality Mobility Test

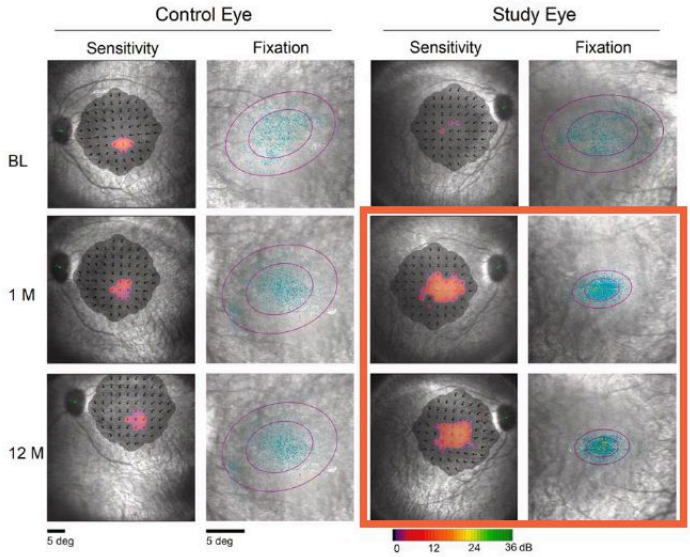




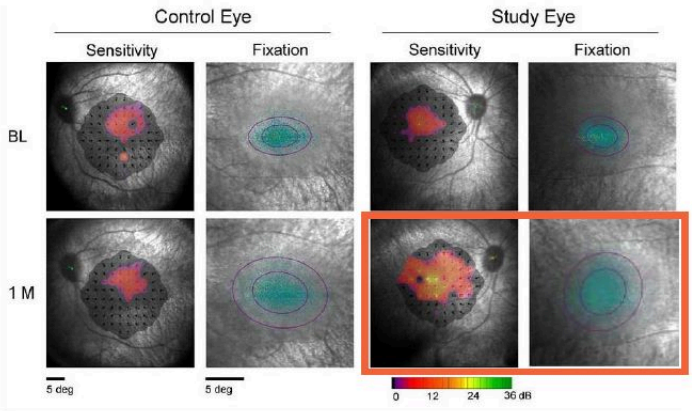
BL, baseline; CFB, change from baseline; M, month; MLoMT, Multi-Luminance orientation and Mobility Test; VA, visual acuity; VR, virtual reality.

OPUS GENETICS

Microperimetry Data Provides Evidence of Increased Sensitivity and Movement of Fixation Toward the Fovea



Adult Participant 01-04



Pediatric Participant 01-06

23 Microperimetry is a detailed, eye-tracking-assisted visual field test that creates a retinal sensitivity map of the macula by testing a patient's response to light at specific points; BL, baseline; M, month.

OPGx-LCA5 Program Positioned for Rapid Advancement

Excellent safety data in all participants with follow-up out to 18 months in adult cohort

Robust biologic activity corroborated through multiple functional outcomes:

- VA and FST improvements in 5 out of 6 participants suggest enhanced visual perception and clarity
- Improvement in MLoMT translates to potential improved ability to navigate the environment and perform daily activities

Rare Pediatric Disease, Orphan Drug and Regenerative Medicine Advanced Therapy designations received from the FDA; potential eligibility for Priority Review Voucher upon BLA approval*

Successful Type B RMAT meeting completed with enrollment ongoing in run-in period for planned, adaptive Phase 3 trial

BLA, Biologics License Application; *Potential PRV opportunities contingent on timing of FDA approval and/or congressional reauthorization of PRV program

Partnered Asset:
Phentolamine Ophthalmic Solution 0.75%

Global Partnership for Phentolamine Ophthalmic Solution 0.75%

*Future double-digit royalty stream & potential development/commercial milestones up to $130M^*

All Three Indications **Have Sizable U.S. Patient Populations**

1 **APPROVED: Pharmacologically-induced mydriasis[1]**

- 100M eye dilations conducted every year[2]

2 **sNDA SUBMITTED: Presbyopia**

- Progressive loss of ability to focus on close objects results in blurred near vision and eye strain
- 133M presbyopes[3]

3 **Phase 3 ONGOING: Dim light disturbances in keratorefractive patients**

- 600-700K laser vision correction procedures per year[4]; 35% of LASIK patients report dim light disturbances[5]

^$10M milestone payment received upon approval of the first indication for Phentolamine Ophthalmic Solution 0.75%; 1. Ryzumvi. Approved for reversal of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) or parasympatholytic agents (e.g., tropicamide) Prescribing Information. Ocuphire Pharma, Inc.; 2023. 2. Wilson FA, et al. *J Ophthalmol.* 2015;2015:435606. 3. Berdahl J, et al. *Clin Ophthalmol.* 2020;14:3439-3450. Phase 3 trial being conducted in keratorefractive patients with visual disturbances under mesopic, low-contrast conditions; 4. Lindstrom RL. *Ocular Surgery News.* April 1, 2019. Accessed February 9, 2025. https://www.healio.com/news/ophthalmology/20190329/millennials-will-be-the-next-target-for-laser-vision-correction 5. Mamalis N. *J Cataract Refract Surg.* 2014;40:343-344. LASIK, laser assisted in situ keratomileusis.

OPUS GENETICS

Differentiated MOA of Phentolamine is Designed to be Well-Suited for Presbyopia and Decreased Visual Acuity Under Low Light Conditions

STUDIES TO DATE HAVE SHOWN:

Favorable tolerability profile, with no reported incidence of retinal tears or retinal detachment, and minimal to no headaches or dimming

Fast onset of action and extended durability, with reduction of pupil size lasting over 20 hours

Once-daily evening dosing enables improved near vision immediately upon awakening

Our Objective

Provide a safe, long-lasting and effective solution that restores near vision and enhances overall visual performance in daylight and low-light conditions

MOA, mechanism of action.

Leveraging an Efficient Platform for Clinical and Commercial Success

Highlights

- Multi-asset pipeline with significant projected data readouts and milestones
- Two lead gene therapy programs in clinical trials with new data expected in 2026
- First mover advantage in target IRDs
- Gene therapy programs target a potential $15 Billion+ U.S.
- sNDA submitted for partnered presbyopia treatment

Financials

- Ticker: IRD
- Pro-forma cash & equivalents as of 9/30/2025: ~$54 million (including $23 million raised in Nov. 2025)
- Runway: Expected funding into H2 2027
- Common shares outstanding: 68,964,208^

Expected Catalysts

- BEST1: Initial data in Q1 2026
- BEST1: 3-month results from Cohort 1 in mid-2026
- LCA5: Phase 3 dosing in H2 2026
- Two additional gene therapy programs enter clinical testing
- Phentolamine Ophthalmic Solution 0.75%: potential presbyopia approval by year-end 2026
- Phentolamine: Phase 3 topline results in dim light disturbances in H1 2026

^Common shares outstanding as of November 10, 2025

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Nasdaq: IRD

"Impossible is a dare to science."

– **Will Reeve, Good Morning America** feature story on Opus LCA5 patient