Hartwell Society

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Cardiovascular Innovation Forum 2026

Report of proceedings and analysis

The Hartwell Society for Cardiovascular Medicine November 2026

Illustrative sample

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About this report

This document is a sample. It demonstrates the format, method and standard of a report of proceedings prepared from the recordings of a scientific meeting. The meeting it describes, the Hartwell Cardiovascular Innovation Forum 2026, is fictional, as are the society, the people, the companies, the products, the trials, the figures and the sources referred to throughout. No statement in this report concerns any real organisation, product or person.

Purpose and scope

A report of this kind sets out what was presented in each session of a meeting, draws together the subjects that recurred across sessions, and distinguishes throughout between what speakers demonstrated with data and what they asserted. The sample covers ten sessions of a half-day meeting: opening and closing remarks, six sessions of company presentations with panel discussion, a keynote lecture by a regulator and an investor panel. Posters and networking sessions are not covered.

How to read this report

The executive summary sets out twelve principal findings. Part One presents eight thematic analyses, each of which follows a single subject across the whole meeting. Part Two is a record of each session in programme order. An assessment of the evidence presented, a calendar of the dates that speakers gave for forthcoming results, and a chapter on developments announced after the meeting follow Part One.

Status of the statements in this report

Statements attributed to a company are that company's own account of its products and results, as given by its representative on the day. Their inclusion does not constitute endorsement by the society. Those that could be checked against a public source, such as a trial registry, a regulator's website or a company's own announcement, were checked: where the public source differs from what was said, the text carries a footnote naming the source. Statements for which no public source exists, including unpublished data, forecasts and opinions, rest on the speaker alone. Statements attributed to an individual are that individual's view. The keynote speaker stated that she was giving her personal views.

Results from animal or laboratory studies are described as preclinical wherever they appear. Where a figure was shown on a slide and was not spoken, the text says so.

Footnotes

Footnotes are used for one purpose: to record a discrepancy. Where a speaker's words differed from the speaker's own slide, where two figures were given for the same thing, where one speaker contradicted another, where a statement was clarified after review of the recording, or where a public source differs from what was said, the main text gives the version treated as primary, which is normally what was said, and the footnote gives the other version.

Basis of the report

The report was prepared from the video recordings of the meeting. The method by which the recordings were transcribed, reviewed, analysed and verified, and the checks applied, are described in the appendix.

Executive summary

The Hartwell Cardiovascular Innovation Forum 2026 brought companies, investors, clinicians and a regulator into one room for an afternoon, on the premise that those who fund, develop, regulate and use cardiovascular treatments rarely meet openly. The product closest to routine use was a device rather than a drug, and the clinicians on every panel returned to the same qualification: longer-acting treatment changes the burden of care without removing it.

Opening the meeting, Professor Annelise Dahlberg identified durability of lipid-lowering treatment as a challenge that "remains still a big challenge" and described inherited cardiomyopathy as an area "turning into real treatment options". The presentations that followed bore both statements out. Orrinvale Medical announced a CE mark for a leadless dual-chamber pacemaker; Halden Pharmaceuticals reported that its oral factor XI inhibitor had met its primary endpoint in a phase 3 trial of 11,400 patients; Vantrel Bio reported lipoprotein(a) lowering above 90% with an outcomes trial fully enrolled. Elsewhere the evidence was earlier: gene therapy for inherited cardiomyopathy rested on cohorts of 7 to 12 patients, and four of the eight emerging companies had no human data at all. The only regulator on the programme, Ilse Vandermeer, spoke in a personal capacity; the positions of regulators and payers were otherwise reported by companies and clinicians.

Principal findings

1

A leadless dual-chamber pacing system is now CE-marked, and its use depends on catheterisation laboratory capacity and training.

Lena Fischer of Orrinvale Medical announced that the Orrinvale Duo received a CE mark on 22 September 2026, with an indication restricted to patients with atrioventricular block and preserved sinus function, and stated that the burden "shifts from the device clinic to the cath lab, it is not removed". In the pivotal DUET study of 415 patients, implant success was 98.3% and freedom from major complications at 12 months 94.1%, both shown on the slide. The figures that 95% of patients achieve atrioventricular synchrony and that 93% of physicians prefer the system were presented in a company video without reference to a named trial.[1]

1 The summary slide shown after the video states "> 90%" for both figures; the video gives 95% and 93%. Neither names a trial.

2

Longer-acting treatment does not remove the requirement for ongoing monitoring.

Professor Sofia Esteves stated that no data support leaving a patient unseen for six months, and that in her reading of earlier data about half of patients in phase 2 needed uptitration; Professor Adaeze Nwosu stated that patients still need monitoring whatever the dosing interval. Miriam Castellanos of Arden Therapeutics did not propose a monitoring schedule for annual dosing. No speaker gave one.

3

Lowering a biomarker is no longer accepted as sufficient evidence of benefit, and the UK health technology appraisal body wants hospitalisation reduction.

Professor Luís Figueiredo stated that the appraisal body wants a reduction in hospitalisation rather than a biomarker, and Nikolai Petrov of Fenwick Bio agreed that transthyretin knockdown will not be accepted as benefit on its own. These are accounts given by clinicians and companies, not statements by the body itself.[2]

4

One oral factor XI inhibitor has phase 3 data against a direct oral anticoagulant and a filing plan.

Owen Price of Halden Pharmaceuticals reported that in OSPREY-AF tabrexaban was non-inferior to a standard direct oral anticoagulant for stroke or systemic embolism (hazard ratio 1.04, upper confidence bound 1.21 against a margin of 1.38), with major bleeding of 1.9% per year against 3.1%. He stated that the US regulator had given the company "a green light" to file on OSPREY-AF alone; this is the company's account of the regulator's position.[3]

5

Gene therapy for hypertrophic cardiomyopathy is approaching pivotal planning; the phase 1/2 data show biomarker and mass changes, not outcomes.

Samuel Whitlock of Calderon Therapeutics reported that 12 patients had been dosed with CAL-201 in CALLISTO-HCM, with a 44% reduction in NT-proBNP at six months in the second cohort and no dose-limiting toxicities. A reduction in left ventricular mass index of 9 g/m2 appeared on the slide and was not spoken. The pivotal study is planned for the second half of 2027.[4]

6

Vantrel reported lipoprotein(a) lowering above 90%, with outcomes unknown until the second half of 2027.

Rachel Adeyemi reported a mean reduction of 94% at week 48 in the phase 2 BIRCHWOOD study of 240 patients, and that the phase 3 outcomes trial SILVERBIRCH-1, of 8,240 patients, is fully enrolled with a readout expected "late next year".[5]

2 On review, the appraisal body's own listing shows its appraisal of a transthyretin silencer from another company as suspended since July 2025; no active appraisal of a medicine for amyloid cardiomyopathy was listed on 2 November 2026. The panel described the position as "in process".

3 The slide gives only "filing planned 1Q 2027". The statement about the regulator was spoken and does not appear on any slide or in any public source found on review.

4 The speaker said "nearly half"; the slide gives 43.8%.

5 The slide gives the readout as "2H 2027". The speaker said "over 90%" for the phase 2 reduction; the slide gives 94%.

7

First approvals in inherited cardiomyopathy were described as imminent, but each dated statement was a hope, a company target or a line on a slide.

Professor Robert Ashcroft stated that Harrowgate Therapeutics had announced positive pivotal results for a gene therapy in Fabry cardiomyopathy and that he "very much hopes" for approval early next year; nothing has been approved. Aisha Rahman of Ebbwater Genetics said EBW-100 "was approved for early access" in two countries, where the company's own slide describes a provisional authorisation with full authorisation pending.[6]

8

Peak oxygen uptake is being adopted as the pivotal endpoint in inherited cardiomyopathy, although many advanced patients cannot perform the test.

Grace Nakamura of Kessler Pharma reported a gain of 1.9 mL/kg/min against placebo in ORCHARD-HCM, and Felix Brandt of Oriel Cardiogenetics described a pivotal design on the same endpoint. Only 2 of the 9 patients in Oriel's LANTERNWAY study completed cardiopulmonary exercise testing.

9

Hypertrophic cardiomyopathy is the most contested inherited indication, and the figures for the oral drug in non-obstructive disease appeared only on the slide.

Nakamura stated that "about 10" interventional trials are running in the disease. The ORCHARD-1 result in non-obstructive disease, a gain of 0.8 mL/kg/min with p=0.238, was shown on the slide while the speaker described "a signal".[7]

10

Approval does not secure access, and one speaker reported that trial capacity is shrinking.

Laure Mercier of Lumavant stated that payers often require different study designs from regulators; Figueiredo cited a heart failure drug available in Switzerland without reimbursement. Daniel Kowalski of Fieldstone Clinical Research stated that the number of compounds in cardiovascular trials has risen "600%" in ten years while quality sites fall away.[8]

11

The European medicines regulator has not yet been asked to qualify an AI tool in cardiology, and its conditions are already specific.

Giving her personal views, Vandermeer stated that no major qualification request has come from cardiology and invited one; the conditions she set out for AI in trial analysis were a frozen model, a frozen data pipeline, pre-specified validation and a clinically relevant endpoint. She put the number of scientific advice procedures involving AI in 2025 at "maybe 12".[9]

6 The slide reads "provisional authorisation under an early-access framework; full authorisation pending". The spoken word "approved" overstates it.

7 A conference report found on review gives the p value as 0.20; the slide gives 0.238. Neither is statistically significant.

8 His own chart runs from about 20 compounds to about 120, nearer 500%. His slides were marked confidential.

9 Her chart shows 13.

12

The one patient who spoke defined success as not getting worse, and did not expect permanence.

Mateus Oliveira, 27, treated with a gene therapy about three years ago, said he had been told at 19 that he would need a transplant, that he can now climb the stairs at university "without stopping on the landing", and that he hopes the treatment "has bought me 10 to 15 years". He did not name the product and gave no clinical measurements.[10]

10 The "10 to 15 years" is his expectation, not time already gained; he added "I don't know if it's forever".

Programme and contributors

The programme of the meeting as published by the society, with the moderators, speakers and panel members of each session. All names are fictional.

Organising committee

The organising committee of the meeting comprised Professor Annelise Dahlberg (President), Professor Rui Castelo (President Elect), Dr Henrik Solberg (co-opted Board member and programme lead), Professor Beatriz Amaral (General Secretary), Professor Oskar Weiland (Past President) and Fiona Garrity (Executive Director).

Programme

Time	Session	Moderators	Speakers and panel members
13:00	Opening		Annelise Dahlberg; Henrik Solberg
13:06	Heart failure with preserved ejection fraction and cardiometabolic disease	Henrik Solberg; Ingrid Haaland	Laure Mercier, Lumavant; David Okonkwo, Serrat Biosciences. Panel: Laure Mercier; Petra Novak, Clarity Function Labs; Catherine Wyndham; Luís Figueiredo
13:32	Lipid-lowering and atherosclerosis	Oskar Weiland; Elena Marchetti	Rachel Adeyemi, Vantrel Bio; Jonas Keller, Marlowe Pharma; Miriam Castellanos, Arden Therapeutics; Tobias Hartmann, Solenne Biologics; Priya Raman, Ravensworth Medical. Panel: the five speakers and Sofia Esteves[1]
14:28	Inherited and rare cardiomyopathies	Mette Kristiansen; Alessandro Conti	Samuel Whitlock, Calderon Therapeutics; Aisha Rahman, Ebbwater Genetics; Nikolai Petrov, Fenwick Bio; Grace Nakamura, Kessler Pharma; Felix Brandt, Oriel Cardiogenetics. Panel: Samuel Whitlock; Felix Brandt; Yusuf Demir, Castlebay Therapeutics; Robert Ashcroft. Guest speaker: Mateus Oliveira, introduced by Henrik Solberg
15:08	Keynote lecture	Annelise Dahlberg; Henrik Solberg; Klaus Reinhardt	Ilse Vandermeer, senior scientific officer at the European medicines regulator, speaking in a personal capacity
15:33	Investor panel	Henrik Solberg; Beatriz Amaral	Emily Thorne, Blackthorn Ventures; Kenji Okada, Harbourline Capital; Clara Fontaine, Ashcombe Partners; Marcus Hale, Castellane Seed Fund[2]
16:20	Arrhythmia and thrombosis	Annelise Dahlberg; Giulia Ferraro	Owen Price, Halden Pharmaceuticals; Lena Fischer, Orrinvale Medical; Anders Lund, Kestrel Electro; Simone Baptiste, Brightwater Genomics; Hugo Meyer, Tessaro Cardio. Panel: Owen Price; Lena Fischer; Viktor Horvath, Cadence Rhythm; Adaeze Nwosu

1 The published programme lists Dieter Vogel as the sixth member of this panel. The chair announced at the start of the session that Sofia Esteves would take his place.

2 The published programme gives Marcus Hale's affiliation as Strategic Horizons, Inc. He stated during the session that his team leads the externally facing functions of the Castellane Seed Fund.

Time	Session	Moderators	Speakers and panel members
17:01	Innovations in imaging, intervention and digital care	Inês Carvalho; Rui Castelo	Johan Pedersen, Wrenfield Imaging; Chloe Barrington, Northgate Sensing; Daniel Kowalski, Fieldstone Clinical Research; Mei-Lin Chao, Corvane Systems. Panel: Rafael Ortega, Castellane Devices; Yannick Dubois; Hana Suzuki
17:30	Rapid fire presentations by emerging companies	Beatriz Amaral; Arjun Mehta. Panel: Katarina Novotna; Marco Benedetti	Ines Lorenz, Aurelian Bio; Pierre Lacombe, Tollan Therapeutics; Andrea Rossi, Mireille Medical; Callum Fraser, Saltmarsh Devices; Jana Tichy, Lumen Therapy; John Carver, Northwind Bioelectric; Ana Pires, Vectorly; Alastair Grant, CardioMetrix (in collaboration with Larkspur Labs)
18:10	Closing remarks		Annelise Dahlberg; Henrik Solberg

Part One: Thematic analysis

In the full report, eight analyses draw together what was said across sessions on a single subject. This sample includes one.

Lipid-lowering and atherosclerosis

Five companies presented in the lipid session, and between them they described three answers to the problem Professor Annelise Dahlberg had named in her opening remarks: a twice-yearly injection against lipoprotein(a), a once-daily oral inhibitor of PCSK9, and a once-yearly injection against the same target. The figures were large and the comparators were placebo. The clinicians on the panel accepted the biology and questioned the follow-up.

Overview

Rachel Adeyemi of Vantrel Bio set out the case for lipoprotein(a) as a target: a survey of cardiologists found that 63% never test for it, and the company's phase 2 study reported a reduction of 94% at week 48.[1] Jonas Keller of Marlowe Pharma reported a 61% reduction in LDL cholesterol at week 12 with the oral inhibitor pendrelvarin, and Miriam Castellanos of Arden Therapeutics reported that a single dose of ancelsiran held LDL cholesterol 52% lower at 12 months.[2] Tobias Hartmann of Solenne Biologics presented an antibody against ANGPTL3, and Priya Raman of Ravensworth Medical a coronary sinus reducer for refractory angina. No outcomes data were presented by any company; the one outcomes trial described, SILVERBIRCH-1, reads out in the second half of 2027.

Lipoprotein(a) is the new target, and the outcomes are two years away

Vantrel's position, raised in several sessions, is that a large population is untreated because it is untested. Adeyemi reported that 88% of patients in the phase 2 BIRCHWOOD study of 240 patients reached a lipoprotein(a) level below 125 nmol/L, and that the phase 3 SILVERBIRCH-1 trial of 8,240 patients, with a primary endpoint of major adverse cardiovascular events, is fully enrolled with a readout "late next year".[3] A substudy in 120 patients reported a 9% fall in plaque volume.[4]

On the panel Professor Oskar Weiland asked whether plaque regression translates into fewer events. Adeyemi said that it is a hypothesis. That exchange is the state of the evidence: a biomarker lowered by more than 90%, a structural change of single figures, and no outcome yet. Kenji Okada of Harbourline Capital, speaking on the investor panel, named lipids as a crowded indication in which understanding one's place in the landscape is the critical question.

1 The speaker said a survey of "over 1,000" cardiologists; the slide gives N=1,062.

2 Marlowe's slide gives 58.7%; Arden's slide gives 51.6%. In each case the speaker rounded upwards.

3 The slide gives "2H 2027".

4 The slide gives 8.4%.

Oral and annual dosing compete on the same target

Two companies presented PCSK9 inhibition in forms that do not resemble each other. Marlowe's pendrelvarin is a once-daily tablet. The phase 2b LANTANA study of 410 patients reported the 61% reduction above, and three phase 3 studies, GRANITE-1, GRANITE-2 and GRANITE-3, began in the third quarter of 2026 on top of statin therapy, with readouts in 2028. Keller described them as "about 2,400 patients each".[5]

Arden's ancelsiran is a once-yearly injection. The phase 2 WINTERGREEN study of 112 patients reported the 52% reduction at 12 months after a single dose, and the phase 3 FALCONER study of 3,000 patients is to start in the first quarter of 2027, shown on the slide. Castellanos stated that patients from the phase 1 study have 7 years of follow-up.[6] Two company videos were played. In the first, four named clinicians stated that 95% of patients achieve annual dosing and 93% prefer it to monthly injections, without naming a trial; the second carried patient quotations with the on-screen notice that the voices were actor portrayals.[7] On the panel Castellanos said that patients with 6 years of follow-up are on their sixth annual dose and that the company has "seen up to 20 doses" in the open-label cohort, which the follow-up period does not allow.[8]

Key point. The headline reductions in this chapter cannot be ranked against one another. Each was measured at a different time point against placebo in a different population, and only one programme has an outcomes trial under way.

Monitoring remains, whatever the interval

The point raised most often by clinicians, in this session and in the arrhythmia session, was that a longer interval between doses is not an interval between visits. Professor Sofia Esteves stated that no data support leaving a patient unseen for six months, and that in her reading of the earlier data about half of patients in phase 2 needed uptitration.[9] Professor Elena Marchetti put the proportion of patients who do not reach their LDL goal on a statin alone at "at least 30 to 40%", without a source. Nobody proposed abandoning statins, and the consensus of the panel was that combinations and longer dosing intervals are additions to the foundation rather than replacements for it.

Vantrel's own real-world claim cut both ways. Adeyemi reported that 47% of patients on injectable lipid therapy are non-persistent by year five, citing a 2025 analysis.[10] The figure supports the case for a less frequent injection, and it also describes the population a less frequent injection will be given to.

Beyond LDL: an antibody and a device

Solenne's tirocimab, an antibody against ANGPTL3 given monthly, reported a 49% reduction in LDL cholesterol at week 24 in 48 patients with homozygous familial hypercholesterolaemia, and a 54% reduction in triglycerides in a phase 2a study in mixed

5 The slide gives 2,350 for GRANITE-1 and 2,410 for GRANITE-2, and lists GRANITE-3 as not yet recruiting; the registry record read on 2 November 2026 agrees with the slide.

6 The slide gives 6 years.

7 The summary slide shown afterwards states "> 90%" for both figures.

8 Settled on review of the recording as a slip for "up to 6".

9 This is her reading of published data, not a figure given by any company.

10 The paper cited on the slide could not be located on review; a separate analysis of the same database gave 72.9%.

dyslipidaemia.[11] Hartmann stated that injection site reactions occurred in "under 3%" of patients and that a depot formulation of an oral follow-on compound, SOL-440, could release drug for up to six months; both statements were spoken only and the compound is preclinical.

Ravensworth's CSR-2 coronary sinus reducer is CE-marked. In the sham-controlled HARBOURLIGHT study, 71% of patients improved by at least one angina class at six months against 45% with sham.[12] Raman stated that the US pivotal study is fully enrolled with a readout in the second quarter of 2027. She also said that the first-generation device "may be more suitable for patients with microvascular angina", where her own description a minute earlier made clear that the second-generation device was meant.'[13]

Matters not addressed

No price was given for any product. No speaker proposed a monitoring schedule for twice-yearly or annual dosing. The comparator in every efficacy figure was placebo on top of statin, and no company compared itself with another. The panel did not discuss how a once-yearly injection would be recorded and followed in routine records, and no payer or health economist was on the programme.

Programmes referenced

Company	Programme	Stage as presented	Principal point
Vantrel Bio	Lirovasiran, lipoprotein(a) siRNA, twice yearly	Phase 3 outcomes trial fully enrolled	94% reduction at week 48 in phase 2; outcomes in the second half of 2027
Marlowe Pharma	Pendrelvarin, oral PCSK9 inhibitor, once daily	Three phase 3 studies started	61% LDL reduction at week 12 in phase 2b; readouts 2028
Marlowe Pharma	Tiravesta, oral lipoprotein(a) reducer	Phase 2 recruiting	160 patients; four phase 3 studies planned, two recruiting
Arden Therapeutics	Ancelsiran, PCSK9 siRNA, once yearly	Phase 3 to start in the first quarter of 2027	52% LDL reduction held at 12 months after one dose
Solenne Biologics	Tirocimab, ANGPTL3 antibody, monthly	Phase 2	49% LDL reduction in homozygous familial hypercholesterolaemia
Ravensworth Medical	CSR-2 coronary sinus reducer	CE-marked; US pivotal fully enrolled	71% improved by one angina class against 45% with sham

11 The slide gives 48.6% for the familial hypercholesterolaemia study. The speaker described that study as "phase 2b"; the slide says "phase 2".

12 The slide gives 70.6% against 44.9%, p=0.0008. The speaker said the study enrolled 250 patients; the registry record gives 240.

13 Settled on review as a slip of the tongue.

Dates to watch

The dates in this chapter were stated by speakers, or shown on their slides, at the meeting on 14 October 2026; they are the companies' own expectations and not confirmed events. Where a speaker said "next year", the entry is placed in 2027 only where the source itself says so, and otherwise appears under the final heading.

Fourth quarter of 2026

When (as stated)	Company	Event	Basis
15 October 2026, the Congress	Orrinvale Medical	Presentation of 7-year data from the earlier single-chamber device	Spoken
24 October 2026	Halden Pharmaceuticals	Full results of OSPREY-AF at the Global Cardiovascular Therapeutics meeting	Spoken and slide
18 and 19 November 2026	European medicines regulator	Data forum	Slide
December 2026	Tessaro Cardio	3-year data from TIDEWATER	Slide
End of 2026	Northgate Sensing	Readout of the US pivotal study of the PulsePoint sensor	Spoken

First half of 2027

When (as stated)	Company	Event	Basis
1Q 2027	Fenwick Bio	Readout of LODESTAR-2	Slide
1Q 2027	Halden Pharmaceuticals	Filing of tabrexaban	Slide
1Q 2027	Arden Therapeutics	Start of FALCONER	Slide
2Q 2027	Kessler Pharma	Filing of tovacamten in the EU	Slide
2Q 2027	Ravensworth Medical	Readout of HARBOURLIGHT-US	Spoken
2Q 2027	Ebbwater Genetics	Submission for EBW-100	Slide

Second half of 2027

When (as stated)	Company	Event	Basis
2H 2027	Vantrel Bio	Readout of SILVERBIRCH-1[1]	Spoken and slide
2H 2027	Calderon Therapeutics	Start of CALLISTO-2	Slide

1 The speaker said "late next year"; the slide gives "2H 2027".

When (as stated)	Company	Event	Basis
End of 2027	Tollan Therapeutics	First human dosing[2]	Spoken

2028 and later

When (as stated)	Company	Event	Basis
2028	Marlowe Pharma	Readouts of GRANITE-1 and GRANITE-2	Slide
2029	Oriel Cardiogenetics	Readout of the pivotal study of ORL-7	Spoken
2029	Calderon Therapeutics	Readout of CALLISTO-2	Slide
2029	Mireille Medical	First clinical use of the MgFlex scaffold	Spoken

Stated without a firm date

When (as stated)	Company	Event	Basis
"Next year"	Kestrel Electro	CE mark for the Kestrel PF-1	Spoken
"Early next year"	Castlebay Therapeutics	Start of a phase 3 study of CBY-01[3]	Spoken
"Already enrolled"	Lumen Therapy	European trial of 120 against 120 patients[4]	Spoken
Not stated	Serrat Biosciences	Decision on a European study of ilmasiran	Spoken
Not stated	Brightwater Genomics	Certification of the HCM screening module	Spoken

2 The company's public statements, found on review, say only that it will be ready to apply for trial authorisation in 2027.

3 The company's published guidance, found on review, was the second half of 2026; no phase 3 study was registered on 2 November 2026.

4 The slide shows enrolment running from August to December 2026 at 9 sites; the registry record read on 2 November 2026 lists 7 sites in Germany and Austria, a start date of 2 June 2026 and a status of recruiting.

Developments since the meeting

This chapter records announcements made after the meeting on 14 October 2026 that bear directly on statements in this report. Each is taken from a public source, which is named, and none formed part of what was presented in Lisbon.

Results published after the meeting

Tabrexaban in atrial fibrillation. At the meeting Halden Pharmaceuticals reported that OSPREY-AF had met its primary endpoint and that major bleeding was "nearly halved", with full results embargoed. According to a company release dated 24 October 2026, the rate of stroke or systemic embolism was 1.21% per year with tabrexaban against 1.16% with the comparator (hazard ratio 1.04, within the non-inferiority margin), major bleeding was 1.9% against 3.1% per year, and discontinuation for adverse events was 4.2% against 4.0%. These figures were read in a syndicated copy of the release and have not been confirmed against the company's own publication; they should be confirmed with Halden before publication.

EBW-100 in Danon disease. On 20 October 2026 Ebbwater Genetics published 24-month data showing stabilisation of left ventricular wall thickness in 5 of 7 treated patients. The slide shown at the meeting stated 6 of 6 evaluable patients at 12 months.

Regulatory position at the date of this report

Tovacamten. On 28 October 2026 Thornbury Pharma stated that the US regulator had accepted its filing for tovacamten with priority review, with a target action date of 12 March 2027. The product is not approved in any jurisdiction.

Harrowgate Therapeutics. The company has stated that it plans a rolling submission later in 2026 for its gene therapy in Fabry cardiomyopathy. Nothing is approved.

Lirovasiran. No readout from SILVERBIRCH-1 had been announced as of 2 November 2026, and the company's guidance is unchanged.

Transthyretin silencers in the UK. The UK health technology appraisal body's listing shows its appraisal of a transthyretin silencer from a company not presenting at the meeting as suspended since July 2025. No active appraisal of a medicine for amyloid cardiomyopathy was listed on 2 November 2026.

The next meeting

The Society has announced that the next Forum will take place on Wednesday 6 October 2027 in Gothenburg.

Part Two: Record of sessions

In the full report, every session is recorded in programme order: what each speaker presented, the evidence shown, and the discussion that followed. This sample includes one.

Inherited and rare cardiomyopathies

Five companies presented gene therapies, a transthyretin silencer and an oral myosin inhibitor for inherited and rare cardiomyopathies, and a patient treated with a gene therapy spoke by video link. The session's evidence was early: the largest gene therapy cohort was 12 patients, and the only phase 3 result presented, for the oral drug, rested on an exercise endpoint that many patients with advanced disease cannot perform.

Samuel Whitlock, Calderon Therapeutics

Whitlock presented **CAL-201**, an intravenous gene therapy delivering MYBPC3 for hypertrophic cardiomyopathy caused by variants in that gene, which he said account for "about 40%" of genotyped disease.[1] In the phase 1/2 **CALLISTO-HCM** study 12 patients have been dosed in three cohorts, with 12 weeks of prophylactic immunosuppression. He reported a 44% reduction in NT-proBNP at six months in the second cohort and no dose-limiting toxicities; a 9 g/m2 reduction in left ventricular mass index appeared on the slide and was not spoken.[2] The slide listed an expedited designation in the US and priority status in the EU. The pivotal CALLISTO-2 study is planned for the second half of 2027 with a readout in 2029. He referred to "around 300 patients" in a natural history study, a figure given only in speech.

Aisha Rahman, Ebbwater Genetics

Rahman presented **EBW-100**, a gene therapy delivering LAMP2 for Danon disease. Seven patients have been treated, and LAMP2 expression was shown on biopsy in 5 of 7. The slide stated that 6 of 6 evaluable patients showed stabilisation of left ventricular wall thickness at 12 months.[3] She said the study included adolescents; the registry record lists adults aged 18 and over. She stated that EBW-100 "was approved for early access" in two countries.,[4] She gave the company's size as "about 80 employees" and said "around 300 patients" had been treated across its programmes; neither figure appears on a slide.

Nikolai Petrov, Fenwick Bio

Petrov presented **dromalsiran**, a quarterly subcutaneous siRNA silencing transthyretin, for transthyretin amyloid cardiomyopathy. The phase 3 **LODESTAR-2** study of 640 patients has a composite primary endpoint of all-cause mortality and cardiovascular events at 30 months, and reported transthyretin knockdown of 91%.[5] The readout is expected "early

1 The slide gives "35 to 40%".

2 The speaker said "nearly half"; the slide gives 43.8%.

3 Data published by the company on 20 October 2026 give stabilisation in 5 of 7 treated patients.

4 The slide reads "provisional authorisation under an early-access framework; full authorisation pending". A submission is targeted for the second quarter of 2027.

next year"; the slide gives the first quarter of 2027. Petrov stated that health technology appraisal bodies do not accept biomarker knockdown as evidence of benefit, which is why the trial measures outcomes. He described a pipeline of "eight" programmes; the slide lists seven.

Grace Nakamura, Kessler Pharma

Nakamura presented **tovacamten**, a once-daily oral cardiac myosin inhibitor for obstructive hypertrophic cardiomyopathy. Kessler is a wholly owned subsidiary of Thornbury Pharma; the slide gives the completion of that transaction as 2 September 2026. In the phase 3 **ORCHARD-HCM** study of 212 patients, randomised 1:1 over 24 weeks, peak oxygen uptake improved by 1.9 mL/kg/min against placebo (p<0.001), with a 48 mmHg reduction in outflow tract gradient at the 14 mg dose.[6] A gain of 9.1 points on the Kansas City Cardiomyopathy Questionnaire appeared on the slide. In the phase 2 ORCHARD-1 study in non-obstructive disease she described "a signal"; the slide gives a gain of 0.8 mL/kg/min with p=0.238. A filing in the EU is planned for the second quarter of 2027, shown on the slide. She introduced herself as chief medical officer; her title slide reads senior vice president, clinical development.

Felix Brandt, Oriel Cardiogenetics

Brandt presented **ORL-7**, a gene-agnostic intravenous gene therapy expressing a protective modifier for genetic dilated cardiomyopathy. In the phase 1/2 **LANTERNWAY** study of 9 patients, ejection fraction improved by at least 6 points in 5 of 9 at six months, which he described as "most patients", with no safety events "of note".[7] Two further programmes, BEACONFIELD and WAYFARER, appeared on the slide without their indications. He stated that the company has raised "about $180 million" and operates its own central testing laboratory.

Discussion

The panel, chaired by Professor Mette Kristiansen and Professor Alessandro Conti, added Yusuf Demir of Castlebay Therapeutics and Professor Robert Ashcroft. Demir stated that in Castlebay's phase 1/2 study of CBY-01 for PRKAG2 syndrome "about two-thirds" of patients showed what he termed approvable levels of improvement in exercise capacity against almost none in the control group, without figures, and that a phase 3 study would start early next year.[8] Ashcroft stated that Harrowgate Therapeutics, which was not presenting, had announced two weeks earlier that its gene therapy for Fabry cardiomyopathy met its primary endpoint, and that he very much hopes for formal approval early next year, first in the US and then in Europe. Nothing is approved. He added that the first patient in that programme was treated in 2017 and that over 200 patients are in a natural history study, both spoken only.

Whitlock offered an anecdote in support of the safety of reducing the target protein: two siblings with no functional protein at all, which in his view makes an 80% reduction safe. Nakamura said that "about 10" interventional trials are running in hypertrophic

5 The slide gives 90.6%.

6 The slide gives 208 patients and a gradient reduction of 46.5 mmHg.

7 The registry record lists the study as phase 1, in adults aged 18 to 70; the speaker said "phase 1/2, all ages".

cardiomyopathy; whether ORCHARD-HCM itself is complete or ongoing was left unclear, the slide saying "ongoing". The panel agreed that peak oxygen uptake is becoming the pivotal endpoint across the field, and that many patients with advanced disease cannot perform the test: only 2 of the 9 patients in LANTERNWAY completed it.

Guest speaker: Mateus Oliveira

Mateus Oliveira, 27, from Portugal, who has Danon disease, joined by video link, introduced by Dr Henrik Solberg. He said that at 19 he was told he would need a transplant, and that about three years ago he received a gene therapy; he did not name the product or the company, and the report does not. He described the change in his own terms: he can climb the stairs at university "without stopping on the landing", and "it's the small things". He said he hopes the treatment "has bought me 10 to 15 years" and that he does not know "if it's forever".[9] He gave no clinical measurements, and none are added here.

8 The company's published guidance, found on review, was the second half of 2026; no phase 3 study was registered on 2 November 2026.

9 The "10 to 15 years" is his expectation, not time already gained. One phrase, "I was stunned", was corrected on review of the recording from a mishearing.

Method and verification

This appendix describes how a report of this kind is prepared from the recordings of a meeting and the checks that are applied at each stage. The figures given are those of the sample.

Sources

The source material is the video recording of each session, amounting in this sample to approximately four and a half hours. The official programme published by the society is used to confirm the names and affiliations of moderators, speakers and panel members. Public sources consulted to verify statements are identified in the footnotes in which they are used.

Transcription and review

The audio of each recording is transcribed by speech recognition software. Each transcript is then compared with the video. Speakers are identified from the captions shown on screen, and the text of every slide is read from the recording so that names, product and trial designations, and figures can be checked against what was displayed. Passages that remain uncertain are extracted as short clips and reviewed by a member of the project team, who listens to each and determines the reading. The outcome of every such review is recorded. In this sample, 67 clips were reviewed.

Extraction of facts

Each transcript is divided into its individual talks and discussions, forty in this sample. Each is read separately, in isolation from the others, so that statements made by one speaker cannot be attributed to another. From each, the individual facts are recorded: the products and mechanisms described, the trials and results reported, the dates given, the regulatory and commercial statements made, and the opinions and challenges voiced. Each fact is recorded with the name of the speaker, the time in the recording and the exact words on which it rests. In this sample this produced a base of 1,641 facts.

Two automated checks are applied. The first confirms that the words quoted in support of each fact appear verbatim in the transcript. The second confirms that every paragraph of every transcript has either given rise to at least one fact or been recorded as containing nothing reportable, so that no part of the meeting is omitted without a decision.

Analysis and drafting

The session records and the thematic analyses are written from the base of facts and not from the transcripts. Every statement in the working papers carries a reference to the facts on which it rests. An automated check confirms, for every line, that the facts cited exist, that every figure in the line appears in those facts in the same form, that anything still unresolved is described as such, and that anything read from a slide and not spoken is identified as coming from a slide. A subject is described as having been raised in several sessions only where three or more separate talks support it.

The chapters of the report are then written from those working papers under the same check. The references to individual facts are retained in the working files and are omitted from the printed text for readability.

Verification against public sources

After drafting, every statement that can be tested against a public primary source is tested. The sources used are, in order of preference, the regulator concerned, the trial registry, the company's own announcement or regulatory filing, and the peer-reviewed publication. Each check is limited to sources retrieved on a stated date, and none relies on recollection.

In this sample, 231 checks were made, covering 361 individual statements. Of these, 108 were confirmed, 74 were confirmed in part, 11 differed from the public source and 38 could not be found in any public source. A further 149 statements were opinions, forecasts or unpublished data, for which no public source can exist. Every difference, and every partial confirmation of importance, is recorded in a footnote that names the source and its date.

The studies named by speakers are matched to their entries on a trial registry and listed in the following appendix. A study is matched only where the sponsor or product on the registry corresponds to the company that named it.

Announcements made after the meeting are not blended into the account of what was presented. They are set out separately in the chapter on developments since the meeting.

Limitations

The report records what was said and shown at the meeting. Verification against public sources establishes whether a statement agrees with what has been published; it does not establish that the published information is itself correct, and it cannot reach data that a company has not made public.

A number of spoken figures do not appear on any slide and could not be checked against a second source. They are reported as the speaker's statement. In panel discussions the recording does not always show who is speaking; speakers are identified from the picture and from the manner in which they are addressed, and a small number of brief interjections cannot be attributed.

Passages that remain unintelligible after review are omitted. The automated checks confirm that the report is faithful to the base of facts. They do not determine which findings are the most important, which is a matter of editorial judgement.

Trials referred to at the meeting

The studies named by speakers, matched to their entries on a trial registry. A study is listed only where the sponsor or product on the registry matches the company that named it. Phase and status are as recorded on the registry on 2 November 2026 and may differ from the description given at the meeting; where they differ materially, the relevant chapter carries a footnote. The registry identifiers in this sample are illustrative.

Study	Sponsor on the registry	Registry identifier	Phase	Status
FALCONER	Arden Therapeutics	TR-2026-0501	Phase 3	Not yet recruiting
WINTERGREEN	Arden Therapeutics	TR-2024-0452	Phase 2	Active, not recruiting
Calderon natural history	Calderon Therapeutics	TR-2022-0033	Not applicable	Completed
CALLISTO-HCM	Calderon Therapeutics	TR-2024-0077	Phase 1/2	Active, not recruiting
Castlebay CBY-01 phase 1/2	Castlebay Therapeutics	TR-2024-0251	Phase 1/2	Active, not recruiting
CorvaneOne first-in-human	Corvane Systems	TR-2025-0260	Not applicable	Completed
EBW-100 phase 1/2	Ebbwater Genetics	TR-2023-0344	Phase 1/2	Active, not recruiting
LODESTAR-2	Fenwick Bio	TR-2024-0301	Phase 3	Active, not recruiting
OSPREY-ACS	Halden Pharmaceuticals	TR-2024-0199	Phase 3	Active, not recruiting
OSPREY-AF	Halden Pharmaceuticals	TR-2023-0120	Phase 3	Completed
Harrowgate Fabry pivotal	Harrowgate Therapeutics	TR-2022-0140	Phase 2/3	Active, not recruiting
ORCHARD-1	Kessler Pharma	TR-2023-0290	Phase 2	Completed
ORCHARD-HCM	Kessler Pharma	TR-2024-0166	Phase 3	Active, not recruiting
Kestrel PF-1 first-in-human	Kestrel Electro	TR-2025-0102	Not applicable	Completed
Lumen Therapy European trial	Lumen Therapy	TR-2026-0330	Not applicable	Recruiting
GRANITE-1	Marlowe Pharma	TR-2026-0209	Phase 3	Recruiting
GRANITE-2	Marlowe Pharma	TR-2026-0210	Phase 3	Recruiting
GRANITE-3	Marlowe Pharma	TR-2026-0211	Phase 3	Not yet recruiting
LANTANA	Marlowe Pharma	TR-2024-0388	Phase 2b	Completed
OAKMOOR	Marlowe Pharma	TR-2026-0147	Phase 2	Recruiting
SORREL	Marlowe Pharma	TR-2026-0318	Phase 3	Recruiting
THISTLE	Marlowe Pharma	TR-2026-0319	Phase 3	Recruiting
PulsePoint registry	Northgate Sensing	TR-2025-0187	Not applicable	Recruiting

Study	Sponsor on the registry	Registry identifier	Phase	Status
STRIDE-HF	Northwind Bioelectric	TR-2022-0219	Not applicable	Completed
STRIDE-HF2	Northwind Bioelectric	TR-2026-0088	Not applicable	Recruiting
LANTERNWAY	Oriel Cardiogenetics	TR-2025-0058	Phase 1	Recruiting
DUET	Orrinvale Medical	TR-2023-0405	Not applicable	Completed
HARBOURLIGHT	Ravensworth Medical	TR-2023-0096	Not applicable	Completed
HARBOURLIGHT-US	Ravensworth Medical	TR-2025-0233	Not applicable	Active, not recruiting
KINGFISHER	Serrat Biosciences	TR-2026-0412	Phase 2	Recruiting
TIDEWATER	Tessaro Cardio	TR-2023-0071	Not applicable	Active, not recruiting
BIRCHWOOD	Vantrel Bio	TR-2024-0113	Phase 2	Completed
SILVERBIRCH-1	Vantrel Bio	TR-2025-0271	Phase 3	Active, not recruiting

Named at the meeting and not matched

- **ROWAN and BRACKEN (Marlowe Pharma).** The registry carries the two further Tiravesta phase 3 studies without their names, so they are not matched by name.
- **Tollan Therapeutics, Mireille Medical and Saltmarsh Devices.** No clinical study is registered; all three companies presented preclinical work only.
- **Castlebay Therapeutics phase 3.** The study described by Yusuf Demir as due to start had not been registered on 2 November 2026.
- **Lumen Therapy pilot study.** Not found on a public register.