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): **April 19, 2023**

COMPASS PATHWAYS PLC
(Exact Name of Registrant as Specified in Its Charter)

England and Wales	**001-39522**	**Not applicable**
(State or other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

33 Broadwick Street
London W1F 0DQ
United Kingdom
(Address of Principal Executive Offices; Zip Code)

+1 (716) 676-6461
(Registrant's Telephone Number, Including Area Code)

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**
American Depositary Shares, each representing one ordinary share, nominal value £0.008 per share	CMPS	The 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.

COMPASS Pathways plc (the "Company") is furnishing an updated corporate presentation, attached as Exhibit 99.1 to this Current Report on Form 8-K (the "Corporate Presentation"), which the Company intends to post on the Company's website and to use from time to time at investor conferences and in meetings with investors and others beginning on April 19, 2023. The Corporate Presentation is current as of April 19, 2023, and the Company disclaims any obligation to update this material in the future.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibits are filed herewith:

Exhibit No.	Description
99.1	Corporate Presentation dated April 19, 2023
104	Cover page interactive data file (embedded within 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 hereunto duly authorized.

COMPASS PATHWAYS PLC

Date: April 19, 2023

By: /s/ Michael Falvey
Michael Falvey
Chief Financial Officer

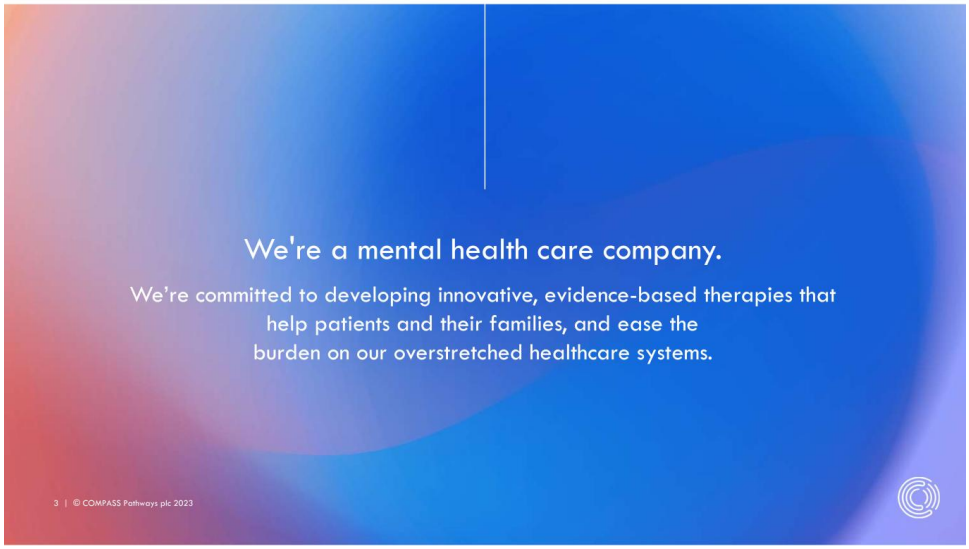

COMPASSION
Navigating Mental Health Pathways
Transforming Mental Health Care
April 19, 2023

Disclaimer

Cautionary Note Regarding Forward-Looking Statements This presentation includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, you can identify forward-looking statements by terms such as "believe," "continue," "could," "estimate," "expect," "may," "might," "plan," "potential," "project," "should," "target," "will," "would," or the negative of these terms, and similar expressions intended to identify forward-looking statements. However, not all forward-looking statements contain these identifying words. These forward-looking statements include express or implied statements relating to our strategic plans or objectives; our plans and expected timing for our phase 3 program in treatment resistant depression and the potential for that or other trials to support regulatory filings and approvals; our expectations regarding amendments to our phase 3 protocols and results of ongoing discussions with FDA; our plans and expected timing for our phase 2 trials in anorexia nervosa and post traumatic stress disorder; our expectations regarding the future reimbursement and accessibility of COMP360 psilocybin therapy, if FDA approval is obtained, including the potential impact of the CPT III codes on such reimbursement and accessibility; our ability to launch and successfully commercialize COMP360 psilocybin therapy; potential revenue streams if COMP360 psilocybin therapy is approved; and our ability to advance COMP360 psilocybin therapy in other areas of high unmet mental health need and to discover and advance new drug compounds. By their nature, these statements are subject to numerous risk and uncertainties, including the impact of global macroeconomic trends on our business, our expectations about the outcomes of our clinical programs, actions of regulatory agencies, our dependence on third parties in connection with our clinical trials and other factors beyond our control, that could cause our actual results, performance or achievements to differ materially and adversely from those anticipated or implied in our statements. For additional disclosure regarding these and other risks we may face, see the disclosure contained under the heading "Risk Factors" and elsewhere in the Company's most recent Annual Report on Form 10-K and subsequent public filings with the US Securities and Exchange Commission (the "SEC"). You should not rely upon forward-looking statements as predictions of future events. Although our management believes that the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Moreover, neither we, nor any other person, assumes responsibility for the accuracy and completeness of these statements. Accordingly, you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact. Except as required by applicable law, we undertake no obligation to update these forward-looking statements to reflect any new information, events or circumstances after the date hereof, or to reflect the occurrence of unanticipated events. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Market & Industry Data Projections, estimates, industry data and information contained in this presentation, including our general expectations about our market position and market opportunity, are based on information from third-party sources, publicly available information, our knowledge of our industry and assumptions based on such information and knowledge. Although we believe that our third party-sources are reliable, we cannot guarantee the accuracy or completeness of our sources. All of the projections, estimates, market data and industry information used in this presentation involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. In addition, projections, estimates and assumptions relating to our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including, but not limited to, those described above, that could cause future performance to differ materially from our expressed projections, estimates and assumptions or those provided by third parties.

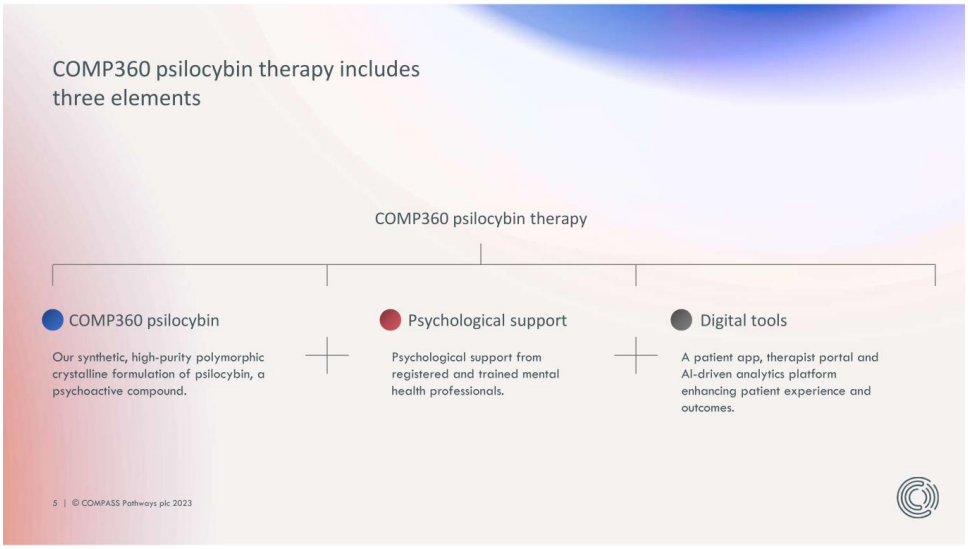
This presentation shall not constitute an offer to sell or the solicitation of an offer to buy securities, nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.


We're a mental health care company.
We're committed to developing innovative, evidence-based therapies that help patients and their families, and ease the burden on our overstretched healthcare systems.
3 | © COMPASS Pathways plc 2023

We have a team of experts and leaders with a record of delivering visionary innovation in pharma and beyond

1. **Kabir Nath**
   Chief Executive Officer
2. **Guy Goodwin, MD, PhD**
   Chief Medical Officer
3. **Trevor Mill**
   Chief Development Officer
4. **Anne Benedict**
   Chief People Officer
5. **Mike Falvey**
   Chief Financial Officer
6. **Matt Owens**
   General Counsel and Chief Legal Officer
7. **Greg Ryslik** Chief Technical Officer
8. **Chris Williams**
   Chief Communications Officer
9. **Ekaterina Malievskaia MD**
   Chief Innovation Officer and Co-founder
10. **George Goldsmith**
    Chairman and Co-founder

COMP360 psilocybin therapy includes three elements



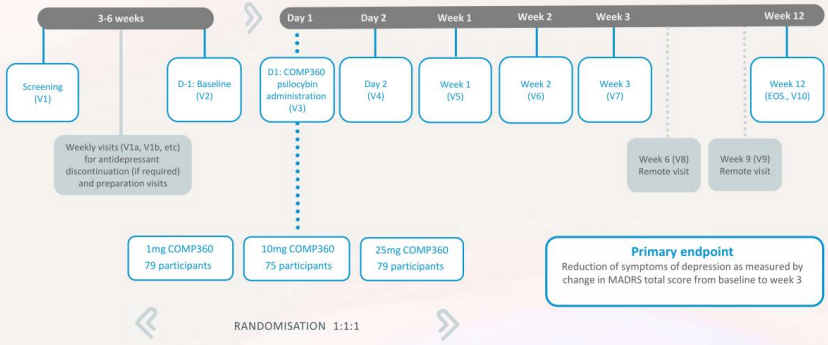
TRD treatment pathway: significant unmet need for 100 million patients

Treatment pathway stage	New onset depression Major depressive disorder (MDD)	Persistent depression Major depressive disorder (MDD)	Treatment-resistant depression (TRD)
Line of therapy	First line	Second line	Third line +
Estimated number of patients (worldwide)	320 million	200 million	100 million (~1 in 3 of total) US health care cost approx. $17-25k per patient/year
Available treatments	– Antidepressants – Psychological interventions, e.g., CBT*	– Antidepressants – Antidepressant combinations – Psychological interventions	– Antidepressants – Augmentation therapy (antidepressants, mood stabilizers, anticonvulsants, atypical antipsychotics, esketamine) – Ketamine – Somatic therapy (rTMS, tDCS, ECT, DBS)* – High-intensity psychological interventions
% relapse	60-70%	50-75%	80-90%

*NOTE: CBT = cognitive behavioural therapy; rTMS = repetitive transcranial magnetic stimulation; tDCS=transcranial direct current stimulation; ECT=electroconvulsive therapy; DBS=deep brain stimulation

SOURCETable adapted from Rush, A. J., Trivedi, M. H., Wisniewski, S. R., Nierenberg, A. A., Stewart, J. W., Warden, D., ... & Fava, M. (2006). Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR* D report. American Journal of Psychiatry, 163(11), 1905-1917; Zhdanava M, Pilon D, Ghelerter I, et al. The prevalence and national burden of treatment-resistant depression and major depressive disorder in the United States. J Clin Psychiatry. 2021;82(2):20m13699.

COMP001 phase 2b study design and primary endpoint (n=233)



Note: MADRS = Montgomery-Åsberg Depression Rating Scale; EOS = end of study; TRD = treatment-resistant depression; D = day; V = visit

Phase 2b trial: Results demonstrate the potential for a rapid, sustained response in TRD

Published in The NEW ENGLAND JOURNAL of MEDICINE

In a randomized, controlled, double-blind trial, three groups of participants were given a single dose (either 1mg, 10mg or 25 mg) of COMP360 psilocybin alongside psychological support.

Results were measured as a change on the MADRS* depression scale from baseline (a day prior to administration) over a 12-week period.

The primary endpoint of this study was the change from baseline in MADRS total score at week 3.

Efficacy: We saw a statistically significant and clinically meaningful reduction in depression symptoms.

Rapid onset of action: The effect occurred the day after the administration.

Durability: We saw a sustained response at week 12 – a positive indication for high potential as a monotherapy.

NOTE: *Least square mean change from baseline in MADRS total score; MADRS = Montgomery-Åsberg Depression Rating Scale

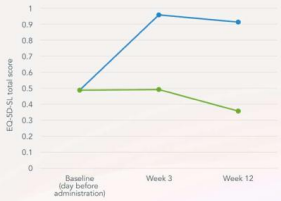
Phase 2b trial: Those participants who showed a sustained response also showed signs of improvement beyond the reduction of depression symptoms

Sustained responders are participants who responded (≥50% change in MADRS total score from baseline) at weeks 3 and 12, and at least one visit out of week 6 and 9, and who did not start new treatments for depression.

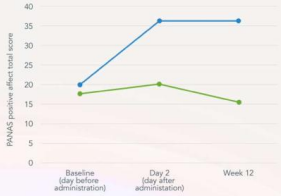
Sustained non-responders are participants who did not respond (<25% change in MADRS total score from baseline) at weeks 3 and 12, and at least one visit out of week 6 or 9.

- Sustained responders (n=19)
- Sustained non-responders (n=21)

Quality of life: Sustained responders were found to have a clinically meaningful increase in quality of life from baseline at week 3 and week 12 with scores in the normal range after treatment



Positive affect: Sustained responders were found to have a clinically meaningful increase in positive affect from baseline on the day after the psilocybin session and at week 3



NOTE: EQ-5D-3L= EuroQol 5-Dimensions 3-Levels; PANAS= Positive and Negative Affect Schedule; SD= standard deviation

Phase 2b trial: COMP360 psilocybin therapy was generally well-tolerated

Treatment-emergent adverse events (TEAEs)

>90% of TEAEs were of mild or moderate severity.

5 most frequent TEAEs across the 10mg and 25mg doses were headaches, nausea, fatigue, insomnia and anxiety.

>77% of TEAEs occurring on the day of administration resolved on the same or next day; most were mild or moderate.

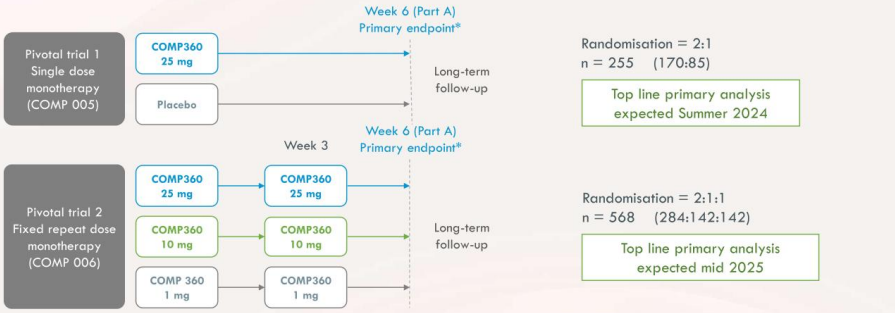
There were no concerns with vital signs, ECG or clinical laboratory data in any of the treatment groups

TEAEs involving hallucinations (which only occurred in the 25mg and 10mg groups) and illusions (all groups) started and resolved on the day of administration.

TEAEs of suicidal ideation, suicidal behavior and intentional self-injury were seen in all groups, as is regularly observed in a TRD population.

- All patients who experienced these events during the trial had said during screening that they had had suicidal thoughts prior to the trial.
- A case-by-case post-hoc analysis of safety data did not establish a causal relationship between these TEAEs and administration of COMP360 psilocybin. The majority occurred more than a week after the psilocybin session.

Phase 3 program: Overview of ongoing pivotal trial designs

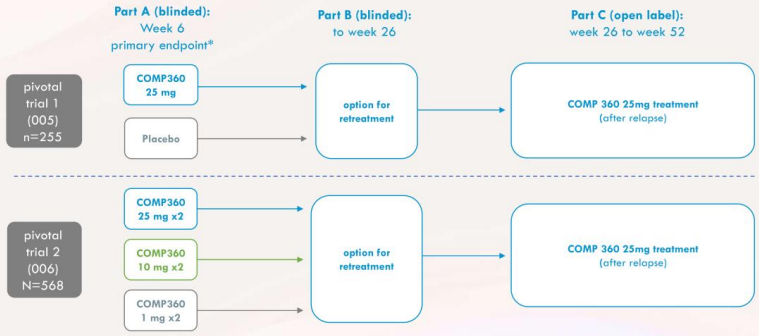


The phase 3 program will be conducted across approx. 150 sites in 12 countries. Key secondary endpoints include change in MADRS at week 9, 6 weeks following second dose. The participant population (TRD definition and core inclusion/exclusion criteria) remains unchanged compared to Phase 2b

*Primary endpoint - change from baseline in MADRS total score at Week 6

Note: We received FDA feedback on the protocol amendments for the COMP 005 and COMP 006 trials. After considering the FDA feedback, we are continuing to conduct the phase 3 program in accordance with our previously announced study design, as revised and presented during our Q4 2022 results call.

Phase 3 program long-term follow up component



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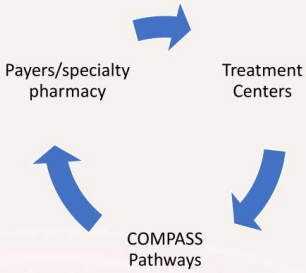
Preparing for scale at launch

COMPASS Pathways intends to deliver COMP360 (medicine) to **Treatment Centers** through specialty pharmacy channels, reimbursed by **Payers**

Our strategy for reimbursement is for **Treatment Centers** to be reimbursed by **Payers** with new reimbursement codes specific to psychedelic therapies*

Regulatory approval and payer coverage/reimbursement is the path to broad and equitable patient access



*New CPT III codes accepted by AMA for Psychedelic Drug Monitoring Services, expected to be released 7/1/23

The infrastructure to deliver COMP360 psilocybin therapy already exists and is growing

- Specialty TRD centers, health systems, and integrated delivery networks (IDNs), some of which are clinical trial sites during phase 3, are already experienced in delivering interventional psychiatry treatments like ketamine, esketamine, transcranial magnetic stimulation (TMS) and electroconvulsive therapy (ECT) to tens of thousands of TRD patients
- These are delivered relatively frequently, requiring a cumulatively high number of hours of patient and provider time

ketamine:
12-15 treatments

TMS:
30-36 treatments

ECT:
6-12+ treatments

esketamine:
20-28 treatments

*treatment #s represent a typical course over 6 months

References: [1] ICER, 2019; [2] Ross, 2018; [3] Petrides, 2011; [4] Thirthalli, 2020; [5] Voigt, 2017

Our digital tools provide educational support and guidance for patients and therapists, enabling the scalability and continuous optimization of our care model

Therapist COMPanion
Web-based portal supporting therapists through all phases of patient care

myPathfinder
Patient-facing app providing guidance throughout COMP360 psilocybin therapy

Chanterelle
AI & analytics infrastructure for continuous optimization

We provide support to research institutions conducting investigator-initiated studies with COMP360 psilocybin

Listed here are signal-generating studies looking at indications in areas of serious unmet need with COMP360 psilocybin.

These studies may provide signals for new potential indications for COMP360 psilocybin that we can explore further and bring into our development pipeline.

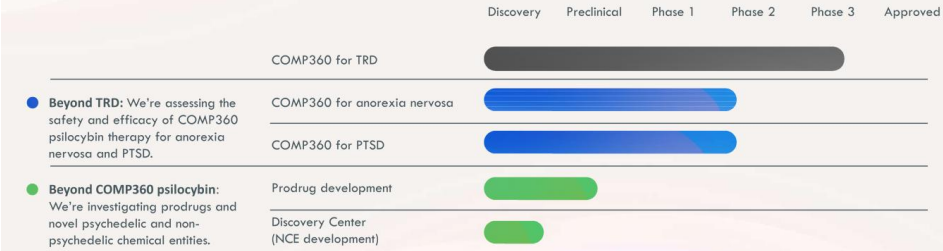
COMPASS owns or has a license to new IP generated around COMP360 psilocybin.

● Complete ● Ongoing

Indication	Institution	Status
MDD in cancer patients	Aquilino Cancer Center	●
MDD	University of Zurich	●
Chronic cluster headache	University of Copenhagen	●
Severe TRD	Sheppard Pratt	●
Anorexia nervosa	UC San Diego	●
Bipolar disorder II	Sheppard Pratt	●
Body dysmorphic disorder	Columbia University	●
Anorexia nervosa	Imperial College London	●
Suicidal ideation	Sheppard Pratt	●
Autism	King's College London*	●
TRD	Stanford	●
Obsessive compulsive disorder	Imperial College London	●
Rumination	Massachusetts General Hospital	●

NOTE: MDD = major depressive disorder ; *A research scientist employed by COMPASS Pathways who is a PhD student at King's College London is conducting the study

We're continuing to develop a balanced and differentiated pipeline



- **Beyond TRD:** We're assessing the safety and efficacy of COMP360 psilocybin therapy for anorexia nervosa and PTSD.
- **Beyond COMP360 psilocybin**: We're investigating prodrugs and novel psychedelic and non-psychedelic chemical entities.

NOTE: NCE = new chemical entity; PTSD = post-traumatic stress disorder; TRD = treatment-resistant depression

COMPASS Financial Overview

Cash and cash equivalents

$143.1 million

Issued shares

42.8 million

Financial guidance for cash used in operating activities

First quarter 2023:	$24 – $32 million
Full-year 2023:	$85 - $110 million

NOTE: Cash and cash equivalents at December 31, 2022. Issued shares as of March 31, 2023; guidance is provided as of February 28, 2023 only

We're a mental health care company.

- Lead product candidate: COMP360 psilocybin therapy
- Phase 2 TRD program published in *The New England Journal of Medicine*
- Phase 3 TRD program recruiting
  - Trial 1: top-line data expected Summer 2024
  - Trial 2: top-line data expected mid-2025
- Phase 2 PTSD study – data expected late 2023
- IIS programs expected to generate data

We're a mental health care company.

We're committed to developing innovative, evidence-based therapies that help patients and their families, and ease the burden on our overstretched healthcare systems.

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