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): August 18, 2025

SOLENO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36593**	**77-0523891**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification Number)**

100 Marine Parkway, Suite 400
Redwood City, CA 94065
(Address of principal executive offices)

(650) 213-8444
(Registrant's telephone number, including area code)

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 symbols	Name of each exchange on which registered
Common Stock, $0.001 par value	SLNO	NASDAQ

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

During August 18-19, 2025, senior management of Soleno Therapeutics, Inc. (the "Company") will participate in previously scheduled meetings with existing and potential investors as part of a non-deal roadshow hosted by Guggenheim Securities and Piper Sandler. A copy of the investor presentation to be used during these meetings is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

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

ITEM 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

SOLENO THERAPEUTICS, INC.

Date: August 18, 2025

By: /s/ Anish Bhatnagar
Anish Bhatnagar
Chief Executive Officer

Corporate Presentation

August 2025 | Soleno Therapeutics

Certain Notices and Disclaimers

Forward-Looking Statements

This presentation contains forward-looking statements that are subject to many risks and uncertainties. Forward-looking statements appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned product development and clinical trials; the timing of, and our ability to make, regulatory filings and obtain and maintain regulatory approvals for our product candidates; our intellectual property position; the degree of clinical utility of our products, particularly in specific patient populations; our expectations regarding adverse events and discontinuation rates; our ability to develop commercial functions; expectations regarding product launch and revenue; our results of operations and cash needs; financial condition, liquidity, prospects, growth and strategies; the industry in which we operate; and the trends that may affect the industry or us.

We may, in some cases, use terms such as "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation.

You should also read carefully the factors described in the "Risk Factors" sections and other parts of our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, available at www.sec.gov, in order to better understand the risks and uncertainties inherent in our business and underlying any forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this presentation will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified timeframe, or at all. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation or to reflect the occurrence of unanticipated events.

Soleno Therapeutics (NASDAQ: SLNO)

Strategic Highlights

VYKAT™ XR approved for treatment of hyperphagia in patients with PWS 4 yrs and older

Approved March 26, 2025

Clinical Trial met primary endpoint with significant differences in hyperphagia

Decades-long safety profile of parent molecule

Significant IP protection

Protected by multiple layers of granted and pending patents

Provides composition of matter protection, as well as protection of formulations and method of use

Potential for substantial patent term extension to mid- late 2030s

Breakthrough, Orphan and Fast Track Designations

Orphan designation in US and EU. Breakthrough and Fast Track granted in US

Significant upside potential in other indications

Orphan designation granted for GSD1a in US

>$2B US PWS market opportunity

Addresses the defining symptom of PWS

Significant commercial potential in PWS, an orphan indication with high unmet need.

VYKAT XR first approved treatment for hyperphagia, the defining symptom of PWS

Strong balance sheet

Cash runway extends beyond launch of VYKAT XR

June 2025 pro forma cash, cash equivalents and marketable securities ~$510m[1]

Sufficient to fund Company well into commercial launch

[1]Includes ~$216m of net proceeds from July 2025 CMPO

PWS, Prader-Willi syndrome

Not for Product Promotional Use

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Prader-Willi Syndrome: A Complex Rare, Genetic Neurobehavioral, Metabolic Disorder with Dire Unmet Needs

Disease Overview

- Due to loss or lack of expression of genes on chromosome 15
- Birth incidence ~1:15,000, diagnosed around birth in most cases
- Characteristics: Hyperphagia, significant behavioral problems, low IQ, low muscle mass, scoliosis
- High mortality rates with mean age of death ~30 years[2] but with many now living into the 50s or longer

Highest Unmet Needs

- Hyperphagia, an insatiable desire to eat, is present in virtually all patients with PWS[1,4]
- Disruptive PWS-related behaviors food and non-food related (e.g. significant aggression leading to ER visits)
- Abnormal body composition with low muscle mass and high fat mass[4]

Burden of Disease

- People with PWS require supervised care for life[1] with children typically living with families and adults often in group homes
- Constant monitoring and creation of food secure zones greatly interfere with activities of daily life
- Caregiver burden is highest after onset of hyperphagia; higher than those measured in caregivers for persons with Alzheimer's[3]
- 92% of the siblings indicated moderate-to-severe PTSD[5]

1. Soleno proprietary quant research
2. Butler MG, et al., Genet Med. 2017 Jun;19(6):635-642.
3. Kayadjanian N et al., PLoS One 2018 Mar 26; 12(3): e0194655
4. Global survey conducted by the Foundation for Prader-Willi Research
5. Mazaheri MM, et al., J Intellect Disabil Res. 2013 Sep;57(9):861-73.

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FDA APPROVED MARCH 26, 2025

vykat™ XR
(diazoxide choline) extended-release tablets

Indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)

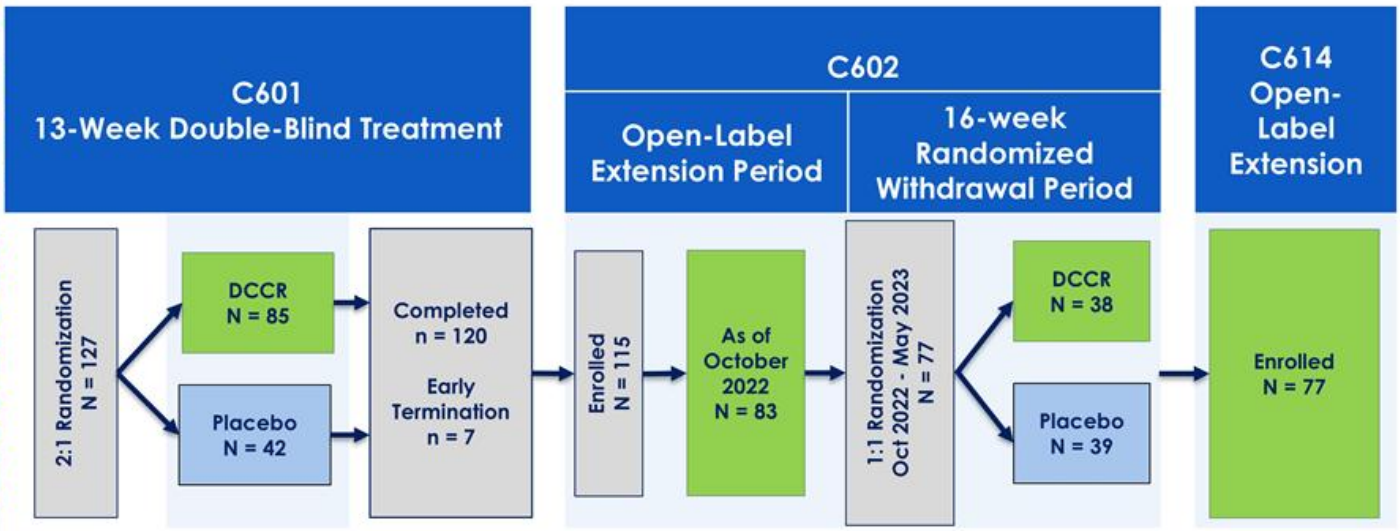
Changing What it Means to Live with PWS

VYKAT XR is the **first-to-market treatment** for hyperphagia in patients with PWS 4 yrs and older

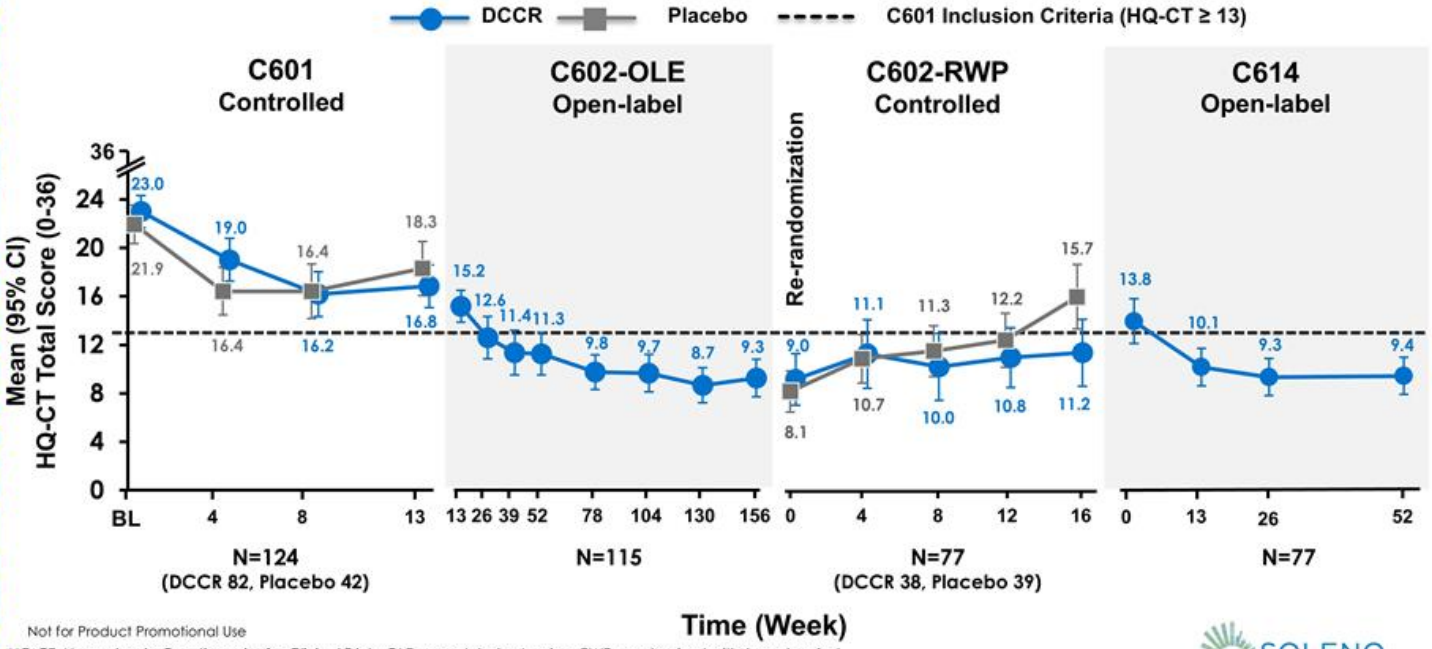
Clinical program demonstrated ability to significantly reduce hyperphagia and impact other PWS-related comorbidities

VYKAT XR can become the foundational therapy for patients with PWS

DCCR Phase 3 Clinical Program



HQ-CT Total Scores Over Time[1, 2]
Studies C601, C602-OLE, C602-RWP, and C614



Not for Product Promotional Use

HQ-CT, Hyperphagia Questionnaire for Clinical Trials; OLE, open-label extension; RWP, randomized withdrawal period

1. Gevers E. Long term efficacy of Diazoxide Choline in participants with PWS from the completed C601 (Destiny PWS) and C602 (OLE). Oral Presentation at European Society of Pediatric Endocrinology Meeting. Nov. 2024; Liverpool, England. 2. Data on File, Soleno Therapeutics, 2025.

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DCCR Safety Profile*

- Extensive clinical trial safety database with >100 PWS patients treated >1 year
  - >440 total person-years of experience overall
  - Includes patients with >6 years of continuous exposure
- Safety profile generally consistent with prior experience with DCCR and the known profile of diazoxide
- The most common adverse events reported were hypertrichosis, edema, and hyperglycemia
- Typically self-limiting, some needing dose adjustment, interruption, or other treatment (e.g., oral antidiabetics for hyperglycemia or diuretics for edema)
- Notable AEs included serious AEs of erythema multiforme & diabetic ketoacidosis (1 event each)

* AEs reported in DCCR Clinical Trial Program and described in the VYKAT XR US Package Insert

Glycemic Outcomes of Diazoxide Choline Extended-Release (DCCR) Tablets Administered for Hyperphagia in Individuals with Prader-Willi Syndrome Over 4 Years: ENDO July 2025
Long-term Administration of Diazoxide Choline Extended-Release Tablet (DCCR): ENDO July 2025 (Available at https://investors.soleno.life/presentations/scientific-posters-presentations)

Scientific Outreach & Community Engagement

Continued engagement with PWS community, HCPs and PAOs

Growing body evidence presented at medical and scientific conferences by key opinion leaders and study physicians

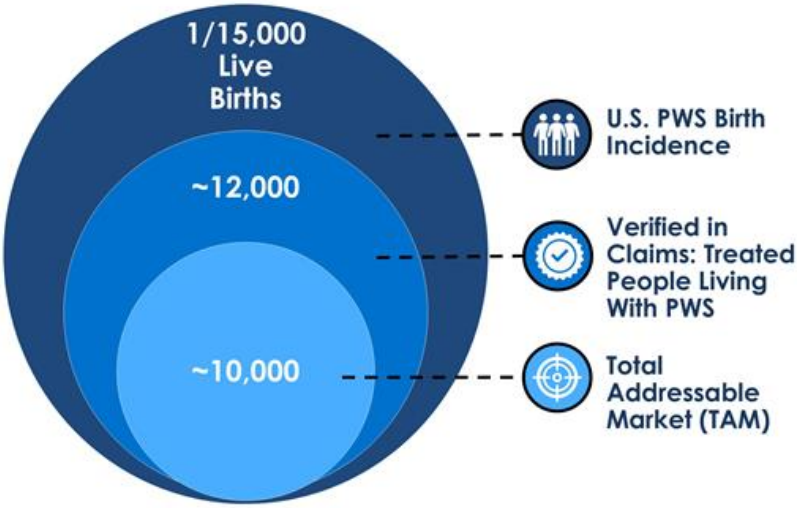
Engage and support the PWS community by attending local, state and national patient advocacy meetings, conferences and events

Created a Community Council that has 20 members of the PWS community of which 3 are adults with PWS – members provide feedback on initiatives, programs and materials

Partnering with PWSA | USA to support the PWS community's advocacy such as those related to Medicaid and recognition of PWS as a disability

HCP, Healthcare Professionals; PAO, Patient Advocacy Organization

VYKAT XR Indication Presents a Significant Commercial Opportunity



- **Diagnosis Rate ~85% of diagnoses** are made within the first year of life[1]
- **Total On-label Addressable Market** Estimated **~10,000 people** with PWS 4 years of age and older with hyperphagia and no exclusionary comorbidities
- **~300 HCPs are primary treaters of ~2,100 PWS patients** and influence treatment decisions for an additional ~2,000 patients[2]

1. *Wheeler, A.C., Gantz, M.G., Cope, H. et al. J Neurodevelop Disord 15, 37 (2023)*
2. *ICD10 claims data – Soleno purchased data*

Pathway to Successful US Launch of VYKAT XR

Robust Clinical Program

- Differentiated formulation
- Efficacy observed in multiple aspects of the disease in clinical trials
- ~5 years of response in clinical trial data
- Well characterized response profile

Rare Disease & Launch Capabilities

- Invested in analytics to map TAM
- Account profiling to define influence and catchment areas
- Field Force teams with deep rare disease and launch experience

Comprehensive Access Strategy

- Mapped payer mix to support rapid uptake
- Educating payers on value proposition
- Distribution partners with extensive rare disease experience

Stakeholder Engagement

- Deep community and advocacy engagement
- Launched Disease State Education programs www.support4PWS.com
- Strong presence at medical congresses

Launch Strategy Requires Specific Considerations for Different Age Groups

Young patients (4 to 25 years old)

01

- Onset of hyperphagia and increasing disruptive PWS-related behaviors
- Caregivers and families are actively engaged in care (~4 visits/year)[1]
- Majority live with family, with support from schools
- Pediatric Endocrinologists are primary point of care, with support from multiple specialties

Adult patients (>25 years old)

02

- Transition to adult care disrupts continuity of care, coincides with increased desire for independence
- Lack of independence; reliant on food-security and 24/7 monitoring
- Majority of adults still live with family members, with ~20% individuals living in residential programs[2]
- Adult Endocrinologists are the primary treaters, mostly focused on mitigating health deterioration

1. *Soleno proprietary quant research*
2. *ICD10 claims data*

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Broad Reimbursement Supported by Clear Clinical Value Proposition for VYKAT XR

Communicate compelling value proposition to gain payer coverage

- **Urgent need for hyperphagia treatment: severe burden and high mortality rate**
- **Robust and durable clinical data supporting significant effect on hyperphagia with VYKAT XR**
- **Rare disease with small patient numbers leading to low budget impact**
- **VYKAT XR is the first and only FDA approved medication for treatment of hyperphagia in people with PWS**

Soleno One™ Provides End-to-End Patient Support

- Limited Distribution Model
- Soleno One™ live Day 1 of Launch
- First prescription sent by April 14th

SOLENO one™

1-833-SOLENO-1

Access. Education. Resources.

Positioned To Be The Standard of Care

vykat™ XR
(diazoxide choline) extended-release tablets

Once daily oral dosing

First and only approved treatment for hyperphagia in individuals 4 years of age and older with PWS

- **Approval based on comprehensive clinical trial program**
- **Key elements of VYKAT XR label**
  - No exclusions for severity of hyperphagia
  - No Boxed Warning
  - No Risk Evaluation and Mitigation Strategy
  - No contraindications
  - VYKAT XR should not be substituted with diazoxide oral suspension
- **Available in the U.S. as of April 10, 2025**

Launch to End of Q2 2025 Performance Metrics

- **5.2 % adverse event related discontinuations as of August 15, 2025**

Significant Opportunity in Europe

- Confirmed high unmet need
- Strong thought leader support
- Concentrated market driven by centers of excellence
- Estimated ~9,500 people living with PWS in EU4 and UK[1]
- In May 2025, we announced submission and EMA validation of MAA

1. *Orpha Net Birth Prevalence of 1/22.5k*

Extensive IP Protection

Three families of patents prosecuted in major pharma markets – primary cases in all three issued

Uses of pharmaceutical formulations of K_{ATP} channel activators

PWS relevant claims: treatment of hyperphagia in PWS with diazoxide

20-Year Expiration 8/2025

Salts of K_{ATP} channel activators and uses thereof

PWS relevant claims: composition of matter (salt and polymorph), formulation, method of manufacture, methods to treat overweight, obese and obesity prone individuals

5 US patents
20-Year expiration12/2026

Potential expiration w/PTA 3/2029

Potential expiration w/PTA & PTE 2034

Methods to treat PWS Patients

Specific claims to behavioral, body composition, and cardiometabolic marker changes in response to treatment with DCCR, diazoxide or K_{ATP} channel activators, dependent claims to treating hyperphagia

4 US patents + 1 application

20-Year expiration 11/2035

Potential expiration w/PTE 2038/2039

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Financial Highlights

Cash, cash equivalents and investments

June 30, 2025	Cash in millions
Pro forma cash[1]	$509.5
Debt	$50.0

[1] Includes marketable securities and $215.7m from July 2025 public offering

Fully Diluted Share Count

June 30, 2025	In millions
Common stock	50.4
Pre-funded warrants	0.3
March 2022 warrants – $4.50	0.5
Options and RSUs	3.9
July 2025 public offering	2.7
Pro Forma Total	**57.8**

Corporate Presentation

August 2025 | Soleno Therapeutics