UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

on Behalf of Itself and All Others Similarly Situated, Plaintiff, vs. SOLENO THERAPEUTICS, INC., ANISH BHATNAGAR, JAMES MACKANESS, and MEREDITH MANNING, Defendants.	Case No. CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS DEMAND FOR JURY TRIAL

Plaintiff ("plaintiff"), on behalf of itself and all others similarly situated, by plaintiff's undersigned attorneys, for plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through plaintiff's attorneys, which included, among other things, a review of U.S. Securities and Exchange Commission ("SEC") filings of Soleno Therapeutics, Inc. ("Soleno" or the "Company"), the Company's press releases, analyst reports, media reports, and other publicly disclosed information about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

This is a securities class action on behalf of all purchasers of Soleno common stock between March 26, 2025 and November 4, 2025, both dates inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "1934 Act") against Soleno and certain of the Company's executive officers.

JURISDICTION AND VENUE

The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder, 17 C.F.R. §240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act, 15 U.S.C. §78aa.

Venue is proper in this District pursuant to 28 U.S.C. §1391(b), and §27 of the 1934 Act, because certain of the events or omissions giving rise to the claim occurred in this District, including the dissemination of the statements alleged to be materially false and misleading into this District, and Soleno is headquartered in this District.

In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

Plaintiff City of Pontiac Police and Fire Retirement System, as set forth in the certification attached hereto and incorporated by reference herein, purchased Soleno common stock during the Class Period and has been damaged thereby.

Defendant Soleno is a pharmaceutical company focused on developing therapies for rare diseases and is headquartered in Redwood City, California. At the time of filing this complaint, the Company's only commercial product is diazoxide choline extended-release tablets ("DCCR") for the treatment of hyperphagia in individuals afflicted with Prader-Willi syndrome ("PWS"). Soleno common stock trades on the NASDAQ stock exchange under the ticker symbol "SLNO."

Defendant Anish Bhatnagar ("Bhatnagar") served as the Chief Executive Officer ("CEO") and Chairman of the Board of Directors of Soleno during the Class Period. Bhatnagar personally oversaw the team responsible for developing and commercializing DCCR.

Defendant James (aka Jim) Mackaness ("Mackaness") served as the Chief Financial Officer ("CFO") of Soleno during the Class Period. On February 25, 2025, Soleno announced that CFO Mackaness would be retiring by the end of the Company's first quarter of 2026.

Defendant Meredith Manning ("Manning") served as the Chief Commercial Officer ("CCO") of Soleno during the Class Period.

Defendants Bhatnagar, Mackaness, and Manning are collectively referred to herein as the "Individual Defendants."

Each of the Individual Defendants was directly involved in the management and day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, services, competition, customers, and present and future business prospects, as alleged herein. In addition, the Individual Defendants were involved in drafting, producing, reviewing, and/or disseminating the false and misleading statements and information alleged herein, were aware of, or recklessly

disregarded, the false and misleading statements being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

As officers and controlling persons of a publicly held company whose securities are registered with the SEC pursuant to the 1934 Act and trade on the NASDAQ, which is governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations, business, services, markets, competition, customers, and present and future business prospects. In addition, the Individual Defendants each had a duty to correct any previously issued statements that had become materially misleading or untrue, so that the market price of Soleno common stock would be based upon truthful and accurate information. Defendants' false and misleading misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, were able to, and did, control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading before or shortly after their issuance, participated in conference calls with investors during which false and misleading statements were made, and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each Individual Defendant is responsible for the accuracy of the public statements detailed herein and is, therefore, primarily liable for the representations contained therein.

BACKGROUND

Soleno is a biopharmaceutical company focused on developing novel therapeutics for the treatment of rare diseases. Soleno (fka as Capnia, Inc.) in its current iteration arose out of its 2017 merger with Essentialis, Inc. ("Essentialis"), a privately held company. CEO Bhatnagar oversaw the merger with Essentialis and the transition of Soleno from a company previously focused on the screening, detection, and treatment of medical conditions to one focused on

developing DCCR, trademarked as "VYKAT XR," a potential treatment for individuals with PWS and hyperphagia that Soleno had acquired from Essentialis.

PWS is a rare genetic condition caused by the loss of function of specific genes on chromosome 15. In babies, symptoms include weak muscles, poor feeding, and slow development. Beginning in childhood, those affected become constantly hungry – a condition known as hyperphagia – which can lead to obesity, type 2 diabetes, cardiovascular disease, and mortality (*e.g.*, stomach rupture, choking, accidental death due to food-seeking behavior). Mild to moderate intellectual impairment and behavioral problems may also occur in affected individuals, who often display common physical characteristics such as a narrow forehead, small hands and feet, short height, light skin and hair, and sterility.

Prior to the start of the Class Period, there were no U.S. Food & Drug Administration ("FDA")-approved treatments for individuals with PWS suffering from hyperphagia. An estimated 300,000 to 400,000 individuals suffer from the condition worldwide. DCCR thus represented a promising potential breakthrough for this rare genetic condition.

DCCR consists of the active ingredient diazoxide choline, a choline salt of diazoxide, which is a benzothiadiazine. The Company has stated that DCCR appears to act by stimulating ion flux in adenosine triphosphate ("ATP")-sensitive potassium channels, which in turn affects PWS symptoms in a variety of ways, such as suppressing certain neuropeptides involved in appetite and satiety, decreasing insulin and leptin resistance, and reducing the accumulation of excess body fat.

In June 2020, Soleno announced that a Phase 3 trial for DCCR had failed to meet its primary endpoint of change from baseline in hyperphagia among the patient population. Nonetheless, the Company claimed that significant improvements were observed in two of three key secondary endpoints: (i) improvement in clinical global impression score (a measure of symptom severity) as assessed by the investigator; and (ii) reduction of body fat mass as measured by a dual-energy X-ray absorptiometry ("DXA") scan.

In September 2021, Soleno announced interim one-year data from the C602 open-label extension ("OLE") study to the Phase 3 trial, which the Company claimed showed

statistically significant reduction from pre-DCCR baseline in mean hyperphagia scores and all other PWS behavioral parameters and statistically significant improvements compared to the natural history of PWS over a one-year treatment period.

In March 2022, Soleno submitted an amended protocol to the FDA that incorporated a randomized withdrawal ("RW") period to the C602 OLE study that sought additional controlled data as requested by the FDA, with the Company claiming that the FDA had acknowledged the potential for the study extension to address its concerns about DCCR's efficacy. The RW period consisted only of patients previously enrolled in the C602 study.

On September 26, 2023, Soleno announced positive statistically significant results for the primary endpoint from the RW period. According to the Company, hyperphagia-related behaviors markedly worsened in the placebo group after they stopped taking DCCR compared to those who remained on DCCR, evidenced by a "highly statistically significant, clinically meaningful difference in mean change from baseline in the HQ-CT total score of 5.0 at week 16 ($p=0.0022$)." The Company further claimed that DCCR "continued to be generally well-tolerated in the randomized withdrawal period with no new or unexpected safety signals, including no serious adverse events or discontinuations due to adverse events occurring in any participants in the DCCR group."

On April 29, 2024, Soleno announced that the FDA had granted Breakthrough Therapy Designation to DCCR. According to Soleno, the designation reflected the FDA's determination that, based on an assessment of the preliminary data from the Company's Phase 3 clinical development program, diazoxide choline may demonstrate substantial, clinically significant improvements over available therapies.

On June 27, 2024, Soleno submitted a New Drug Application ("NDA") to the FDA for DCCR on the basis of Soleno's Phase 3 clinical program, including the OLE and RW study extensions.

On August 27, 2024, Soleno announced that its NDA for DCCR had been accepted by the FDA with an initial target action date of December 27, 2024, which was subsequently extended to March 27, 2025.

MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS ISSUED DURING THE CLASS PERIOD

The Class Period begins on March 26, 2025. On that date, Soleno issued a press release announcing that the FDA had approved DCCR to treat hyperphagia in individuals with PWS based on results from the Company's Phase 3 program, which include the C602 study and RW period. The press release stated in pertinent part:

> The FDA approval of VYKAT XR was based on ***an adequate and well-controlled study and safety data from the comprehensive clinical development program***. Efficacy was established during the 16-week randomized withdrawal study period of Study 2-RWP (Study C602-RWP), a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial. Individuals randomized to switch to placebo demonstrated a statistically significant worsening of hyperphagia compared with individuals who remained on VYKAT XR. Prior to participating in the randomized withdrawal period, all individuals received double-blind and/or open-label VYKAT XR for a mean duration of 3.3 years.
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> ***VYKAT XR has a well-established safety profile with over four years of data across four double-blind and/or open label studies. The primary safety analyses are based on Study 1 (Study C601) and the most common adverse reactions occurring in greater than or equal to 10% of individuals receiving VYKAT XR and at 2% greater than placebo included hypertrichosis, edema, hyperglycemia and rash***.

That same day, Soleno held a conference call with analysts and investors to discuss the FDA approval of DCCR, which was hosted by CEO Bhatnagar and CCO Manning. In his prepared remarks, CEO Bhatnagar highlighted the purported strength of the Phase 3 extension study as underpinning the FDA's approval of DCCR, stating in pertinent part:

> As a reminder, ***our approval is based on a comprehensive data package that includes statistically significant data from a Phase 3 study showing that patients in placebo had significantly more hyperphagia than those on VYKAT XR in a randomized withdrawal study***.
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> We're pleased with the label we've received. The indication is for the treatment of hyperphagia in adults and pediatric patients four years of age and older with PWS, which is consistent with our expectations. ***Our label reflects VYKAT's favorable safety and tolerability profile, contains no [box] warnings, no contraindications for diabetes, no exclusions for severity of hyperphagia, and no requirement for a risk evaluation and mitigation strategy or REMS program***.

On May 7, 2025, Soleno issued a press release for the Company's first fiscal quarter ended March 31, 2025. In the release, CEO Bhatnagar was quoted as stating: "'During the first quarter of 2025, we achieved the most significant milestone in the history of our company with

FDA approval of VYKAT XR for the treatment of hyperphagia in patients four years and older with Prader-Willi syndrome . . . .'" CEO Bhatnagar continued in pertinent part:

> "While it has only been a few weeks since we announced approval and commercial availability, the high level of interest that we are experiencing, as reflected in both patient start forms and unique prescribers, reflects the significant unmet need that VYKAT XR can address as a first-to-market treatment for this debilitating condition. With a strong balance sheet and a world class team, I believe ***we are very well positioned to sustain our current momentum, delivering VYKAT XR to the patients who need it while creating significant long-term value for our company***."

That same day, Soleno held a conference call with analysts and investors to discuss the Company's first quarter results, which was hosted by CEO Bhatnagar, CFO Mackaness, and CCO Manning. During the call, CEO Bhatnagar highlighted the fact that the label for DCCR purportedly "reflects VYKAT XR's favorable safety and tolerability profile, contains no box warning, no contraindication for diabetes, no exclusions for severity of hyperphagia, or no requirement for a risk evaluation and mitigation strategy or REMS program."

Also on May 7, 2025, Soleno filed with the SEC a quarterly report on Form 10-Q for its first fiscal quarter, which was signed by CFO Mackaness and certified by CFO Mackaness and CEO Bhatnagar as true, materially complete, and free from fraud. The Form 10-Q stated: "On March 26, 2025, the Company announced that its lead product candidate, VYKAT™ XR (diazoxide choline) extended-release tablets, formerly known as DCCR, had been approved by the U.S. Food and Drug Administration (FDA)." The Form 10-Q further stated that this approval was given because Soleno had persuasively demonstrated the safety and efficacy of DCCR through rigorous clinical trials, stating in pertinent part:

> ***Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we will be required to demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses***.

On June 10, 2025, CFO Mackaness presented to investors and analysts on behalf of Soleno at the Goldman Sachs Global Healthcare Conference. Referring to the purported success of the C602 study, CFO Mackaness represented: "We read out strongly statistically significant results on the hyperphagia measurement. That's what we use to form the basis for our NDA. . . .

We're going to C602, the randomized withdrawal phase, and you see what you'd like to see is those on placebo worsening, going up to 15.7, those on drugs staying constant." CFO Mackaness downplayed the safety risks observed during the Company's Phase 3 clinical program, stating in pertinent part:

> ***Regarding the safety profile for DCCR, extensive clinical trial safety database with greater than 100 PWS patients treated for over a year, safety profiles consistent with the parent molecule dioxide***.
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> The most common adverse events reported were hypertrichosis, edema, and hyperglycemia, but ***typically, self-limiting could do some dose adjustment or a drug holiday***, and in certain situations, maybe oral anti-diabetics for hyperglycemia.
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> ***During the entire length of the clinical program, only two severe AEs have been reported to date***. Throughout that time, we've continued engagement with the PWS community, HCPs, and patient advocacy groups. We have very good relationships, growing body of evidence presented at medical and scientific conferences by KOLs.

On July 10, 2025, Soleno issued a press release providing preliminary financial and operation results for the Company's second fiscal quarter ended June 30, 2025. The release stated that Soleno expected net revenue from its sales of DCCR during the quarter to be between $31 million and $33 million.

The next day, July 11, 2025, Soleno filed with the SEC a final prospectus on Form 424B5 to a previously issued shelf registration statement (the "Prospectus") for a secondary public offering of Soleno stock (the "SPO"). Soleno sold over 2.7 million shares of Soleno stock in the SPO at $85 per share for $230 million in gross offering proceeds.

The Prospectus provided the preliminary net revenue Soleno had derived from the sale of DCCR during the first quarter of $31 million to $33 million. The Prospectus also favorably described the Company's Phase 3 clinical trial program for DCCR, stating in pertinent part as follows:

> DCCR has been evaluated in a Phase 3 study (C601 or DESTINY PWS), a 13-week randomized, double-blind placebo-controlled study, which completed enrollment in January 2020, with 127 randomized participants at 29 sites in the U.S. and United Kingdom (U.K.). Participants who completed treatment in DESTINY PWS and sought continued treatment with DCCR were eligible to receive DCCR in a long-term open-label safety extension study (C602). Top line results from DESTINY PWS were announced in June 2020. Although the trial did not meet its primary endpoint of change from baseline in hyperphagia, significant

> improvements were observed in two of three key secondary endpoints. In February 2021, we announced analysis limited to data collected before the onset of the COVID-19 pandemic. ***The analysis of the data through March 1, 2020 showed statistical significance in the primary, all key secondary and several other efficacy endpoints. In September 2021, we announced top line results from the interim one year data from C602 showing statistically significant reduction in hyperphagia and all other PWS behavioral parameters and statistically significant improvements compared to natural history of PWS from the PATH for PWS Study (PfPWS) over a one year treatment period***.
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> In March 2022, we submitted a proposal to add a randomized withdrawal period to Study C602 to obtain additional controlled data requested by the FDA to support approval of an NDA for DCCR. The randomized withdrawal (RW) period of Study C602 was a multi-center, randomized, double-blind, placebo-controlled study of DCCR in approximately 80 patients with PWS at 17 sites in the U.S. and 5 sites in the U.K. This RW period consisted only of patients currently enrolled in Study C602 and did not enroll any new patients. We announced the initiation of the RW period for Study C602 in October 2022. ***On September 26, 2023, we issued a press release announcing positive topline results from the RW period to Study C602. We announced that the study had met the primary endpoint and that there was a highly statistically significant difference in the change from baseline in HQ-CT Total Score for DCCR Compared to placebo (p=0.0022)***. Further we announced that we intend to submit an NDA for DCCR for treatment of PWS mid-year 2024. The FDA has acknowledged that data from the study has the potential to support an NDA approval for DCCR.

On August 6, 2025, Soleno issued a press release for the Company's second fiscal quarter ended June 30, 2025. The release announced that Soleno had generated $32.7 million in revenue from the sale of DCCR during the quarter and claimed nearly 650 patient start forms and 295 unique prescribers for DCCR since product launch. In the release, CEO Bhatnagar was quoted as stating: "'Our commercial launch of VYKAT XR following the FDA approval in March was a truly transformative milestone for our company, and more importantly, for individuals with PWS and their physicians and caregivers . . . .'" CEO Bhatnagar continued in pertinent part:

> "We are pleased with the initial reception that we are seeing for VYKAT XR, reflecting its position as the very first FDA-approved therapy and the unmet need to treat the hallmark symptom of PWS: hyperphagia. I am very optimistic about our current trajectory and believe that ***we are well-positioned to address the needs of the PWS community while in parallel creating significant and long-lasting value for our company and our shareholders***."

That same day, Soleno held a conference call with analysts and investors to discuss the Company's second quarter results, which was hosted by CEO Bhatnagar, CFO Mackaness, and CCO Manning. During her prepared remarks, CCO Manning stated that "we are still early in

our early phase of launch, and the response from both families and providers has been exceptionally encouraging."

In response to an analyst question, CEO Bhatnagar described DCCR as "on its way to being the standard of care for people living with PWS. It is going to be a therapy that's going to be meaningful. And it's going to be something that PWS patients are going to be on for a long time to come." When asked whether any "pain points" had emerged in the Company's early commercialization efforts, CEO Bhatnagar responded that they had not, stating: "[T]his is a very strong start." CEO Bhatnagar further claimed that "discontinuation rates are substantially lower than what we saw even in clinical trials," evidencing "very high compliance rates" that the Company did not expect "to change significantly." CEO Bhatnagar continued the point when asked about safety observations, stating in pertinent part:

> So, on the safety side, as many of you I'm sure know, monitoring for safety data in the postmarketing setting is quite different from clinical trial settings. So one typically relies on reports from caregivers or healthcare providers, and the patients that you're treating are also often not as controlled and may have more comorbidities, etc.
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> So we are pretty early in the launch, but that said, ***I can tell you that we have not seen anything in the postmarketing setting that is different from the clinical trial setting. So there are no new safety signals. And once again, just to reiterate what we have seen with the discontinuation rates at this time are substantially lower than what we've seen in the clinical trials***.

Also on August 6, 2025, Soleno filed with the SEC a quarterly report on Form 10-Q for its second fiscal quarter, which was signed by CFO Mackaness and certified by CFO Mackaness and CEO Bhatnagar as true, materially complete, and free from fraud. The Form 10-Q stated: "On March 26, 2025, the Company announced that its lead product candidate, VYKAT™ XR (diazoxide choline) extended-release tablets, formerly known as DCCR, had been approved by the U.S. Food and Drug Administration (FDA)." The Form 10-Q further stated that this approval was given because Soleno had persuasively demonstrated the safety and efficacy of DCCR through rigorous clinical trials, stating in pertinent part:

> ***Prior to receiving approval to commercialize any of our planned products in the U.S. or abroad, we will be required to demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and other regulatory authorities abroad, that such planned products are safe and effective for their intended uses***.

The statements referenced in ¶¶25-31, 33-37 above were materially false and/or misleading when made because they failed to disclose the following adverse facts pertaining to the Company's business, operations, and financial condition, which were known to defendants or recklessly disregarded by them as follows:

that the Soleno Phase 3 clinical trial program for DCCR had systematically downplayed, misrepresented, and/or concealed significant evidence of safety concerns potentially related to the administration of DCCR, including issues related to excess fluid retention in clinical trial participants;

that, as a result of (a) above, the administration of DCCR to treat hyperphagia in individuals with PWS posed materially greater safety risks than disclosed by the Company or its executives; and

that, as a result of (a)-(b) above, DCCR had materially lower commercial viability and undisclosed risks related to the likelihood of significant and widespread adverse events after its commercial launch, including risks related to patient discontinuation rates, lower patient adoption, prescriber reluctance, adverse regulatory action, and potential reputational and legal fallout.

Then, on August 15, 2025, Scorpion Capital LLC ("Scorpion Capital") published a sharply critical report regarding Soleno, DCCR, and the Company's Phase 3 clinical trial program, titled "Russian Roulette With Prader-Willi Children: How The Latest Rare Disease Price-Gouging Scheme Fleeced the FDA, Parents, And Its Own Study Investigators With A Worthless, Toxic Drug; Suspect Data; And Sham Clinical Trials To Push A $500K/Year Knockoff Of A 50-Year-Old Generic Compound – Triggering One Of The Worst Launch Failures And Safety Catastrophes In Post-Approval History" (the "Scorpion Capital Report"). Scorpion Capital describes itself as an "activist short sell[er] focused on publicly traded frauds and promotes . . . specializ[ing] in intensive, differentiated research which uncovers what investors have missed and Wall Street is paid to ignore." Scorpion Capital's founder and Chief Investment Officer, Kir Kahlon, is a Harvard Business School graduate and prominent investment manager who previously worked at Bain & Company and with activist investor Carl Icahn and who has been a featured speaker at

Harvard Business School's MBA and Executive Education programs, Columbia Business School, and the Stockholm School of Economics, among other venues.

The 415-page Scorpion Capital Report presented an extensively researched and exhaustively detailed exposé on problems with Soleno's clinical trial conduct, safety and efficacy concerns with DCCR, and patient reports of serious adverse reactions related to the drug following its commercial launch. The report detailed interviews with multiple investigators reportedly involved in conducting the Phase 3 trial, Soleno employees, medical professionals, and key opinion leaders ("KOLs"), presented numerous examples of parents documenting severe harm to their children after administering DCCR, and analyzed the safety and efficacy of DCCR as represented in Soleno's published clinical trials and as compared to available generics. Key findings of the report included, *inter alia*:

> **2. Key trial investigators broadly rebuke VYKAT XR as a failure and looming safety disaster**
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> Investigators indicate that they have no plans to prescribe the drug; that they are advising other physicians to refrain; that they were troubled by Soleno's conduct during the trials; and indicated a general lack of enthusiasm within the field and among their patients. We interviewed every study investigator willing to speak with us (8 in total, plus a 9th who was not a PI but otherwise played a key role). The nearly-universal rejection of a newly-approved drug by some of the most influential figures in the field – who co-authored its papers and collectively treat a significant percentage of PWS patients in the US/UK – strikes us as unprecedented.
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> **3. Endocrinologists who treat PWS patients indicate similar skepticism as trial investigators**
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> We interviewed 11 physicians in-depth, who provided color on a larger sample of endocrinologists from group meetings or recent key conferences (PES), across a broad, representative sample including division chiefs at major academic centers; specialists at leading PWS clinics such as CHOP, MGH, Univ of Michigan, and others; and even among private practice and community doctors, whose in-depth knowledge and rejection we find particularly telling. The few who have submitted meaningful numbers of start forms indicated they only did so because of pressure from desperate families; and that they expect little interest beyond an initial bolus of families willing to try anything new.
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> **4. Safety disaster #1: VYKAT XR drives high risk of pre-diabetes/diabetes**
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> Long-term, mechanism-based blockade of insulin-secretion by diazoxide in patients with normal insulin levels is highly likely to promote type 2 diabetes, particularly in PWS with obese phenotype. Soleno's inept efforts to obscure the diabetes signal suggest the magnitude of the problem. Soleno also buries the risk of diabetic ketoacidosis (DKA), which requires hospitalization and can present with hyperosmolar hyperglycemia state (HHS). Both are life-threatening complications.

Our analysis of the data buried in Soleno's papers suggests an alarming spike in prediabetes and diabetes within 13 weeks of starting VYKAT XR – and a linear increase over 3 years with no signs of a plateau. Recent papers which attempt to downplay the risk exhibit inconsistencies suggestive of potential data fabrication or scientific misconduct. In addition, most PWS patients are on growth hormone as standard of care (ITT 84%), synergistically increasing the risk of diabetes.

5. Safety disaster #2: VYKAT XR drives high of risk of pulmonary edema and congestive heart failure

Fluid retention is inherent to diazoxide's mechanism of action, setting the stage for a safety crisis driven by pulmonary edema, congestive heart failure, and inability to walk due to swollen extremities. We are under the impression, per interviews with investigators and ex-employees, that two patients in the 13-week phase 3 trial (n=85 on drug) may have been admitted for symptoms consistent with pulmonary edema and potential heart failure, but that the event(s) may have been downplayed. The prevalence of edema appears to increase the longer the drug is used, with no apparent plateau – indicating that a tipping point is eventually reached whether discontinuation or a safety event. We think that Soleno has obscured the alarming level of fluid retention by conflating it in its studies as an increase in lean body mass (LBM) – our interpretation of the data indicates a shocking 16 lb steady and linear increase over 3 years of drug – recently, parents on FB are reporting 10-15 lbs of fluid within weeks. In addition, VYKAT XR in conjunction with growth hormone synergistically increases the risk of edema.

6. Largest Facebook group for VYKAT XR discussion suggests a safety crisis and patient backlash

The tone in the primary VYKAT XR group has turned sharply negative in recent weeks, after being ambivalent to negative during May/June, as reports of edema and other adverse events began to surge, such as inability to walk or put on shoes doe [sic] to fluid build-up, hospitalizations for potential heart failure, blood sugar spiking to pre-diabetic and diabetic levels, with posts already piling up of parents indicating they have discontinued the drug or considering it. In the last few weeks, the 4 posts with the most engagement and comments are sharply negative. The general ratio of negative/ambivalent comments to positive ones suggests to us that Soleno's launch has already hit the wall, as the initial bolus of desperate parents dries up – and that the game may already be over for Soleno before it has even begun.

7. Soleno's clinical trials were a sham that make a mockery of the scientific method

The 13-week Phase 3 trial was a failure that showed lack of improvement in hyperphagia, despite the low bar created by a subjective caregiver questionnaire as the primary endpoint (HQ-CT). The FDA was then poised to reject the drug, but relented after a petition campaign by two key PWS associations, allowing Soleno to proceed with a highly unusual 16-week randomized withdrawal study that is the basis of approval and therefore the pivotal trial. The withdrawal study was small (n=77), unusually skewed toward one site, exhibits red flags for suspect data/results, with ex-employees and others involved in the trials expressing concern about potential practices at the largest enrollment site. Most investigators were sharply critical: an unreliable HQ-CT survey instrument; placebo bias due to unblinding via clear side effects (hairiness/edema), as well as a different smell between drug and placebo; alleged pressure to downplay adverse effects, and a lack

of data transparency. We identify other areas of concern: 1) the primary endpoint HQ-CT exhibits a pharmacodynamically implausible relationship with the drug; 2) invalid endpoints created an illusion of efficacy with no valid endpoints left; 3) contradictory efficacy claims across trials; and 4) failure to report or measure key biomarkers.

8. VYKAT XR is a flimsy IP ploy, repurposing an old generic into an inferior tablet formulation

Even if VYKAT XR was safe and effective, off-label substitution by generic diazoxide suspension or an inexpensive branded version called Proglycem would decimate any commercial opportunity before it even begins – a dynamic with plenty of recent precedent. VYKAT XR is an extended-release tablet version of diazoxide, which has been used for 50 years in liquid form in a hospital setting to treat hyperinsulinemia. Soleno's entire existence is predicated upon claims of superior pharmacokinetic characteristics of its tablet. Our PK analysis and modeling – led by a PhD in pharmacology with decades of experience conducting PK studies – leads us to conclude that Soleno's PK data is phony and designed to fabricate a pretense for its tablet, obscuring that suspension and its tablets are freely interchangeable to the point the PK curves are superimposable; that regular diazoxide is actually superior from a PK standpoint and can also be dosed once a day for PWS; and that suspension is safer than tablets. Endocrinologists interviewed indicate significant skepticism of Soleno's rationale for its tablet; state they would be inclined to prescribe suspension off-label instead; and expressed concerns about the size of Soleno's "horse pill" as a hazard as choking is the 4th leading cause of death in PWS children.

9. Ex-Soleno employees and others close to the trials corroborate safety and other concerns

We interviewed four individuals who played key roles in facilitating the trials, including three ex-employees and a KOL, who confirmed investigator skepticism and added other damning detail: pressure from the highest levels to conceal toxicity and serious adverse events; suspicious conduct by the largest enroller and other issues with the trials; leaders in the field refusing to touch the drug due to fear of diabetes and edema/heart failure; and exhibited overall skepticism of the drug's mechanism of action, trial data, and other concerns.

10. VYKAT XR faces severe commercial obstacles, beyond safety and physician skepticism

First, Soleno is unusually dependent on its lead investigator in driving interest for VYKAR XR among endocrinologists and PWS patients nationally – creating substantial risk as the investigator is involved with various competing PWS trials. Second, insurers we interviewed significant skepticism of VYKAT XR, consistent with color from endocrinologists who have submitted start forms and indicated supernormal denial rates. Third, PWS patient associations indicate tepid interest toward VYKAT XR among their members, and significant awareness of adverse effects – the PWS space revolves around two key associations which serve as hubs and resources for families. Fourth, we note a small TAM given the actual breakdown of the PWS patient market, as well as broad interest among endocrinologists in using GLP-1's in PWS.

Among the most damaging evidence for the Scorpion Capital Report's claims were reprinted portions of interviews with key investigators who reportedly worked on the clinical trials for DCCR, as described by the Scorpion Capital Report in pertinent part:

> Trial investigator #1: One of the most prominent, published, and influential authorities in Prader Willi Syndrome; involved with a dozen clinical trials in the past; directly treats or monitors >100 PWS patients – one of the largest caseloads in the field; advises other PWS practitioners around the world. Long history with Soleno and played a key role in the Vykat trials; co-author on trial paper.
>
> – Thinks that Vykat is a failure and has no effect on hyperphagia or weight; that it is dangerous and at risk of an existential Zafgen-type safety debacle; has no plans to put any patients on it; thinks that Soleno played games with the data; and that it should never have been approved by the FDA, which he believes was due to pressure from desperate families: "I didn't see $500,000 worth of – or $5,000 worth of benefit"; "I've been around a long time. I won't use it."
>
> – Stated that he's working on a paper about cardiac risk from Vykat: "I have more than concern about it . . . in fact, I'm writing an article on it . . . I've been asked to write my opinion on this trial in the medical literature"; "yeah, lots of different issues . . . we still don't have a clear understanding, even though the drug has been around since 1976."
>
> – Indicated the trials were just statistical artifacts with no observable difference in patients whether hyperphagia or weight; would advise other physicians to avoid using the drug: "I would say hold off . . ."; "I just didn't think it worked . . ."; "they got a statistician who did all this remarkable testing and, oh, we came up with something . . . I think they played with the data until they finally got something that worked."
>
> – Indicated widespread skepticism in the field of Vykat by other trial investigators and PWS specialists who collectively manage a large percentage of the patients; expects it to be a dud within 3 to 6 months as failures and safety issues mount; "I don't think anyone would say 'Whoa, we got to get these patients on this drug . . . look what it can do . . . a lot of people are taking a hands-off, let's just see . . . I haven't heard from people with much enthusiasm"; "those who are the most experienced are probably not as excited about it than those that are newer . . "
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> * * *
>
> Trial investigator #2: Prominent investigator on multiple Vykat trials and co-author on trial paper; a leading key opinion leader in the field at one of the largest PWS centers in the US, with ~120 patients. Skeptical of Soleno with no interest in prescribing Vykat, to the point of exhibiting anger and alarm at the drug.
>
> – Indicated that almost every patient from the trials discontinued the drug with only one remaining, despite being one of the largest US centers. The investigator hasn't even bothered to discuss Vykat with other endocrinologists at the center since FDA approval, evincing utter dismissiveness; and indicated equal disinterest among colleagues: "I have not really talked to colleagues . . . and one endocrinologist said she did not see a big difference. . . she just said a lot of her patients didn't respond . . ."

– Slammed the drug's price as well as its lack of effect and toxicity – "I was horrified" – and exhibited resentment that "two of my patients developed diabetes . . . and others developed hyperglycemia" while on drug; stated that diabetes risk is inherent to Vykat's mechanism of action: "hyperglycemia . . . which it's supposed to do. I mean, it's not surprising that it causes that because that's the role of the drug."

* * *

– Speculated that Soleno removed critical investigators as authors on papers and buried them under acknowledgments, and played hardball by keeping them in the dark about the status of the papers: "I was very critical, and they didn't want to talk about the side effects, which I insisted on . . . they didn't even tell us that those papers were being prepared or published . . . there were complications . . . they develop hairiness . . . they develop diabetes. . . they develop edema . . . we had to give diuretics"; "co-authors were not even informed about the existence of this [sic] papers"; "it's bizarre . . . [redacted] would have recruited a big number, yet [redacted's] name is not on the paper . . . very odd . . . it was very odd . . . ."

Trial investigator #3: Longtime, globally-recognized authority on Prader-Willi Syndrome; "publishing in this area for 20 or 30 years" with a particular focus on hyperphagia; extensively involved with key PWS associations in advisory or leadership roles; "I'm asked to speak to parents, but quite often I speak to clinicians." Has a long history with Soleno – "very much involved with Soleno over the years" – including the phase 3, open-label, and withdrawal studies.

– The investigator thoroughly trashed Vykat and the clinical trials, stating he saw no benefit in any of his enrollees; that he "encouraged them not to continue" into the open-label extension; that only one patient remains on drug, for a discontinuation rate of ~80%; and that he is skeptical of the mother's perception of benefit in the one remaining patient on the drug.

* * *

Trial investigator #4: Endocrinologist who is a globally-recognized authority on Prader-Willi Syndrome with ~75 patients; co-author on Vykat trial paper who participated in the phase 3, open-label, and withdrawal studies with a significant number of patients enrolled.

– Condemned Vykat as an utter failure on all counts with a 100% patient discontinuation rate – "none of mine continued on it either because they didn't want to or not having much effect – overall this isn't a miracle drug, that's for sure"; "they stopped it because they just didn't see any benefit . . . it wasn't doing much and they were still very obese . . . they didn't feel it worthwhile with the ongoing assessments and all the rest of it . . . the benefits were not seen to be good enough to continue on it."

* * *

Trial investigator #5: Influential key opinion leader with >40 PWS patients currently and 100-150 historically. A large enroller in the Vykat trials and co-author on the papers. Follows a larger group of PWS patients nationally and is a member of a collaborative of 25-35 leading PWS practitioners who manage ~25% of all patients in the US – "they all each have 50 or so patients they follow."

– Involved in the Vykat phase 3, open-label, and withdrawal studies and indicated a massive patient discontinuation rate with only 2 of ~10 enrollees still remaining on drug, due to serious adverse effects, continued weight gain, and/or lack of effect.

* * *

Trial investigator #6: Clinician and researcher with ~30-35 PWS patients and participated in the phase 3, open-label, and withdrawal studies.

– Harshly criticized the Soleno trials; implied that all or most patients discontinued Vykat and dropped out of the trial; indicated "massive concern" about cardiac risk and pulmonary edema; and stated that generic diazoxide liquid suspension is "always going to be better" anyway.

* * *

Trial investigator #7: Co-author on Soleno trial paper and a key opinion leader with ~40 PWS patients at one of the largest clinics; developed the PWS treatment guidelines. Participated in the phase 3, open-label, and withdrawal studies.

– Highly skeptical of the phase 3 trial and especially the "unusual" withdrawal study that was the basis of FDA approval, stating the data was unreliable; that he didn't see a change in his patients; that confounding factors made the hyperphagia questionnaire scores dubious; that the trial had a "strong placebo effect"; and that the HQ-CT instrument was flawed due to inflated baseline scores, subjectivity, and was not a "true genuine score" – "there was not a huge difference in my patients . . . so really, what was the improvement?"; "all these drugs have a strong placebo effect . . . you could argue that it was placebo effect"; "placebo withdrawal which is unusual in terms of trials . . . an unusual study plan . . . that's unusual."

The Scorpion Capital Report also documented interviews with former Soleno employees who criticized the conduct of the trial, claiming that the Company had attempted to downplay the adverse effects of DCCR and that many lead investigators did not believe in its safety or efficacy, and who reportedly stated in pertinent part:

"Very candidly, I'm kind of surprised that the FDA gave them an approval . . . other physicians are not so bullish about it . . . if you talk to some of the other investigators other than Jennifer Miller, you might get a different impression . . . I would say that you have a substantial number of investigators who are not so bullish about the drug"; "I fail to see how any third-party payor would accept this as a treatment . . . it's a little bit like the Sarepta drug . . . you have one devastating DKA and heart failure . . . they had some serious adverse effects where somebody was admitted to the ICU . . . I find it difficult to think that they will be able to really penetrate even a limited market . . ."

"There was certainly some pressure on all the investigators to downplay the adverse effects"; "I was extremely uncomfortable with the direction from [redacted] to try and downplay things . . . it's not what I would do . . . it's not what

> most normal companies would do . . . they wanted a successful outcome . . . all the people with significant incentive were the ones driving this train . . .”
>
> * * *
>
> “I think people are highly incentivized to downplay things that could be on the fence . . . when you have a causal relationship, uncertain or not known, then they decide to not include those type of things in publications.” . . . “The atmosphere at the company was very much to downplay the adverse effects.” . . . “There was a lot of pressure to not have the investigator assessment [of an adverse event during the study] to be causally related to the study drug.”

The Scorpion Capital Report also provided screen shots from social media posts by concerned parents who reported severe adverse effects on their children following the administration of DCCR treatment shortly after commercial launch, including, *inter alia*:

On this news, the price of Soleno common stock declined from a high of more than $77 per share on August 14, 2025 to close at approximately $68 per share on August 18, 2025, a decline of nearly 12% over two trading days on above-average trading volume. However, the price of Soleno common stock remained artificially inflated as the full truth regarding safety data

and risks associated with DCCR was not disclosed to investors and defendants continued to make materially false and misleading statements.

After the Scorpion Capital Report was issued, Soleno executives met with analysts and investors to attempt to refute the report's accusations. According to media reports, CEO Bhatnager stated: "We take safety seriously, and we fully recognize that once you get into a commercial setting, things will be different. . . . Overall, what we're seeing is consistent with the drug's label."

On August 21, 2025, Scorpion Capital submitted a Citizen Petition to the FDA requesting that the FDA "issue a regulation, request recalls, revise industry guidance, and take such other actions" as deemed necessary in response to the findings published in the Scorpion Capital Report.

On September 10, 2025, Soleno filed with the SEC a current event report on Form 8-K disclosing that a patient had died after taking DCCR, which was signed by CEO Bhatnagar (the "Form 8-K").

On this news, the price of Soleno common stock declined from more than $70 per share on September 9, 2025 to close at approximately $57 per share on September 11, 2025, a decline of approximately 19% over two trading days on above-average trading volume. However, the price of Soleno common stock remained artificially inflated as the full truth regarding safety data and risks associated with DCCR was not disclosed to investors and defendants continued to make materially false and misleading statements.

The Form 8-K stated that the "treating physician has reported the case as not related to treatment with VYKAT™ XR and Soleno's assessment is the same." The Form 8-K further emphasized the purported safety of DCCR, stating in pertinent part:

> ***VYKAT XR has a proven safety and efficacy profile and was approved by the FDA following a rigorous clinical program***. Like any medication, VYKAT XR should be administered in accordance with its FDA-approved label, which describes anticipated side effects. Soleno Therapeutics is committed to reporting all adverse events experienced by individuals who have taken VYKAT XR in accordance with applicable law. Prader Willi Syndrome is a disease where patients have significant comorbidities and have a markedly reduced life expectancy due to reasons that can include cardiac or respiratory events as well as others such as pulmonary embolism. The mean age of death reported from a 40-year mortality

> study in the U.S. was 29.5 ± 15 years (range: 2 months-67 years). Going forward, Soleno does not intend to specifically comment on adverse events cases (including deaths) unless directly related to VYKAT XR use and unexpected per the U.S. Prescribing Information.
>
> The existence of a report in the FAERS database does not establish causation. The FDA's website makes this clear: "For any given report, there is no certainty that a suspected drug caused the event. While consumers and healthcare professionals are encouraged to report adverse events, the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons." Additionally, the FDA states "Submission of a report does not mean that the information included in it has been medically confirmed nor it is an admission from the reporter that the drug caused or contributed the event."

On September 11, 2025, Scorpion Capital issued a social media post questioning Soleno's claims that the patient death was not attributable to DCCR, citing prior findings of Soleno's lead investigator that purportedly had established a clear association between edema and embolism in PWS patients.

Scorpion Capital continued to track reports of adverse events related to DCCR, writing on social media on or about October 29, 2025 that a "massive dump of adverse event reports" had been recently uploaded to the FDA's Adverse Event Reporting System Database. According to Scorpion Capital, 83 adverse events had been reported in total, with 20 classified as serious. Scorpion Capital has subsequently reported that these numbers have since increased to 282 total cases, which includes 57 serious cases and 1 death.

Then, on November 4, 2025, Soleno reported its financial results for its third fiscal quarter ended September 30, 2025. CEO Bhatnagar revealed that the Scorpion Capital Report had caused a "disruption" in DCCR's launch trajectory and concerns within the PWS community, with a lower number of patient start forms and increased discontinuations beginning after the report's publication.

Also on November 4, 2025, Scorpion Capital reposted a mother's social media post reporting that her son had suffered congestive heart failure after taking DCCR, reprinted in pertinent part below:

> My son **** 36 (almost 37!!), deletion, started Vykat 9 weeks ago. The first 7 weeks went really well. A few pounds gained with each increase, then lost in a few days. No biggie. When he got to his maintenance dose (450mgs) water retention reared its ugly head. Didn't go back down like it usually did. I reached out to his endo requesting an rx for Lasix. No response. I reached out 4 or 5 times to no avail. Finally on Saturday after a total weight gain of 26 lbs of fluid, we ended up in the ER. **** is still in the hospital. Today is Tuesday. He's being treated with IV Lasix and some heart meds because his heart rate was up to 180 causing him to have Afib. They're calling it Congestive Heart Failure. That's so freakin scary!!! Thursday his cardiologist will perform a cardioversion to shock his heart back into regularity. Then fingers crossed he'll come home.
>
> I really wanted to be one of the moms that had super good things to say about this drug and my son's progress. I really believe that if his endo had responded in a timely manner, my son would not be in the hospital right now. I have yet to hear from him even now. Im really angry.
>
> Thank you for listening,
>
> ****'s mom."

On this news, the price of Soleno common stock declined from nearly $64 per share on November 4, 2025 to close at approximately $47 per share on November 5, 2025, a one-day decline of approximately 27% on above-average trading volume.

As a result of these serial revelations, the price of Soleno common stock has declined significantly from a Class Period high of more than $90 per share to lows of less than $45 per share – a 50% decline and a fraction of the SPO price – causing plaintiff and the Class (defined below) to suffer hundreds of millions of dollars of damages under the federal securities laws. Notably, the price of Soleno common stock has not recovered from the price of the stock prior to the publication of the Scorpion Capital Report despite efforts by the Company to refute the report's allegations, indicating a broad market consensus that a material portion of the report's claims are credible. Notably, at less than $40 per share, at the time of filing this Complaint the price of Soleno common stock has fallen substantially below the price of the stock immediately prior to the FDA's approval of DCCR when it stood around $50 per share.

CLASS ACTION ALLEGATIONS

Plaintiff brings this action as a class action on behalf of a class consisting of all persons who purchased Soleno common stock during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers, directors, and affiliates of defendants,

at all relevant times, and members of their immediate families, and their legal representatives, heirs, successors, or assigns, and any entity in which defendants have or had a controlling interest.

The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Soleno common stock actively traded on the NASDAQ. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Soleno or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions, including being given an opportunity to exclude themselves from the Class.

Plaintiff's claims are typical of the claims of the members of the Class, as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

whether defendants' statements during the Class Period were materially false and misleading;

whether defendants acted with scienter in issuing materially false and misleading statements during the Class Period; and

the extent of injuries sustained by the members of the Class and the appropriate measure of damages.

A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden

of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

ADDITIONAL SCIENTER ALLEGATIONS

As alleged herein, defendants acted with scienter in that defendants knew, or recklessly disregarded, that the public documents and statements they issued and disseminated during the Class Period to the investing public in the name of the Company, or in their own name, were materially false and misleading. Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements and documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Soleno, and their control over and/or receipt and/or modification of Soleno's allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

The Individual Defendants were each provided with or had access to the information alleged herein to be false and/or misleading prior to or shortly after its issuance and had the ability and opportunity to prevent its issuance or cause it to be corrected. Because of their positions and access to material, non-public information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were false and misleading. As a result, each of the defendants is responsible for the accuracy of Soleno's corporate statements and is, therefore, responsible and liable for the representations contained therein.

The development and commercial launch of DCCR was extremely important to the Company and its executives, including specifically the Individual Defendants, as it was Soleno's only commercial drug product. The Individual Defendants were personally involved in the development and commercial launch of DCCR, with CEO Bhatnagar personally overseeing the acquisition of DCCR from Essentialis, the drug's clinical trial program, and the Company's efforts to navigate the FDA approval process. The Individual Defendants have also held themselves out as persons with intimate knowledge about the Phase 3 clinical trial program for DCCR and its real-

world impact following its commercial launch, speaking about the purported safety and tolerability of the drug during conference calls with investors and analysts and in SEC filings.

Defendants also had the motive and opportunity to commit fraud, with Soleno raising $230 million in gross proceeds in the SPO at $85 per share. The Individual Defendants likewise dumped tens of millions of dollars' worth of Soleno stock during the Class Period at fraud-inflated prices. On March 27, 2025, the day after the FDA's approval of DCCR, CEO Bhatnagar sold over $47 million worth of Soleno stock at prices as high as $72 per share. That same day, CFO Mackaness sold over $6 million worth of Soleno stock at prices as high as $72 per share and CCO Manning sold over $3 million worth of Soleno stock at prices as high as $72 per share. These sales occurred as part of a widespread insider selling spree during the Class Period carried out by Soleno executives and the venture capital firm that initially sold Essentialis to the Company, Vivo Capital, LLC, totaling over $200 million. These sales were suspicious in timing and amount and generally executed at prices that far exceeded the price to which Soleno stock fell at the end of the Class Period.

LOSS CAUSATION

During the Class Period, as detailed herein, defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Soleno common stock and operated as a fraud or deceit on Class Period purchasers of Soleno common stock by failing to disclose and misrepresenting the adverse facts detailed herein. When defendants' prior misrepresentations and fraudulent conduct were disclosed and became apparent to the market, the price of Soleno common stock declined significantly as the prior artificial inflation came out of the price of the stock, as detailed herein. As result of their purchases of Soleno common stock during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

APPLICATION OF THE PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET

At all relevant times, the market for Soleno common stock was an efficient market for the following reasons, among others:

Soleno common stock met the requirements for listing and was listed and actively traded on the NASDAQ, a highly efficient, national stock market;

as a regulated issuer, Soleno filed periodic public reports with the SEC;

according to the Company's quarterly report filed with the SEC on Form 10-Q for the fiscal quarter ended September 30, 2025, Soleno had over 53 million shares of common stock outstanding as of October 31, 2025;

Soleno regularly communicated with public investors via established market communication mechanisms, including the regular dissemination of press releases on national circuits of major newswire services, the Internet, and other wide-ranging public disclosures; and

unexpected material news about Soleno was rapidly reflected in and incorporated into prices for Soleno common stock during the Class Period.

As a result of the foregoing, the market for Soleno common stock promptly digested current information regarding Soleno from all publicly available sources and reflected such information in the price of the stock. Under these circumstances, all purchasers of Soleno common stock during the Class Period suffered similar injury through their purchases of Soleno common stock at artificially inflated prices and a presumption of reliance applies.

A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on defendants' material misstatements and/or omissions. Because this action involves defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects – information that defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pled in this complaint. Many of the specific statements pled herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pled herein, defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and/or the forward-looking statement was authorized and/or approved by an executive officer of Soleno who knew that those statements were false when made.

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

employed devices, schemes, and artifices to defraud;

made untrue statements of material fact or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Soleno common stock during the Class Period.

Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Soleno common stock. Plaintiff and the Class would not have purchased Soleno common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by defendants' misleading statements.

As a direct and proximate result of defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Soleno common stock during the Class Period.

For Violation of §20(a) of the 1934 Act
Against All Defendants

Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

During the Class Period, defendants acted as controlling persons of Soleno within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Soleno, the Individual Defendants had the power and ability to control the actions of Soleno and its employees. Soleno controlled the Individual Defendants and all of its other officers and employees. Defendants were also culpable participants of the fraudulent scheme as detailed herein. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

PRAYER FOR RELIEF

WHEREFORE, plaintiff prays for relief and judgment, as follows:

Designating plaintiff as Lead Plaintiff and declaring this action to be a class action properly maintained pursuant to Rule 23 of the Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel;

Awarding compensatory damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

Awarding plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

Awarding such equitable/injunctive or other relief as the Court may deem just and proper, including permitting any putative Class members to exclude themselves by requesting exclusion through noticed procedures.

JURY DEMAND

Plaintiff hereby demands a trial by jury.

DATED: March 6, 2026