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20 UNITED STATES DISTRICT COURT
 21 NORTHERN DISTRICT OF CALIFORNIA
 22 SAN JOSE DIVISION

23 IN RE PRECIGEN SECURITIES LITIGATION)
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CASE NO.: 5:20-cv-06936-BLF
CLASS ACTION
**DEFENDANTS' CORRECTED
 NOTICE OF MOTION AND
 MOTION TO DISMISS
 PLAINTIFF'S SECOND AMENDED
 CLASS ACTION COMPLAINT**

Hearing Date: April 7, 2022
 Time: 9:00 a.m.
 Courtroom: 3, Fifth Floor
 Judge: Hon. Beth Labson Freeman

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TABLE OF ABBREVIATIONS¹

1		
2	“¶” or “SAC” or “Complaint”	Second Amended Class Action Complaint, filed September 27, 2021 (ECF No. 88)
3	“1,4 BDO”	1,4 Butanediol
4	“2,3 BDO”	2,3 Butanediol
5	“2017 8-Ks”	Forms 8-K filed by the Company with the SEC on May 10, 2017, August 9, 2017, and November 9, 2017
6		
7	“Birn Decl.”	Declaration of Jerome F. Birn, Jr. in Support of Defendants’ Motion to Dismiss Plaintiff’s Second Amended Class Action Complaint
8		
9	“Class Period”	May 10, 2017 to September 25, 2020
10	“CW” or “CWs”	Confidential witness(es)
11	“Defendants”	Collectively, each defendant named in the Complaint
12	“DNA”	Deoxyribonucleic Acid
13	“Exhibit” or “Ex.” or “Exs.”	Exhibit(s) attached to the Birn Decl.
14	“Individual Defendants”	Randal J. Kirk, Andrew J. Last, Rick L. Sterling, and Robert F. Walsh
15	“MBP”	Methane Bioconversion Platform
16	“Motion” or “Mot.”	Defendants’ Motion to Dismiss Plaintiff’s Second Amended Class Action Complaint
17	“Order”	Order Instituting Cease-And-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and-Desist Order issued by the SEC on September 25, 2020
18		
19		
20		
21	“Plaintiff”	Lead Plaintiff Raju Shah
22	“Precigen” or “Company”	Precigen, Inc. f/k/a Intrexon Corporation
23	“PSLRA”	Private Securities Litigation Reform Act of 1995, Pub. L. 104-67, 109 Stat. 737 (codified at 15 U.S.C. §§ 77z-1 and 78u-4)
24		
25	“SEC”	U.S. Securities and Exchange Commission
26		

¹ Citations to Form 8-Ks (Exs. 6, 7, 9-10, 12, 18-19, 22, and 28) refer to ECF-designated page numbers. Citations to all other Exhibits refer to the document’s internal page numbers.

1 **NOTICE OF MOTION AND MOTION**

2 PLEASE TAKE NOTICE that, on April 7, 2022, at 9:00 a.m., before the Honorable Beth
3 Labson Freeman of the U.S. District Court for the Northern District of California, 280 South 1st
4 Street, San Jose, CA 95113, Fifth Floor, Courtroom 3, Defendants Precigen, Inc. f/k/a Intrexon
5 Corporation, Randal J. Kirk, Rick L. Sterling, and Andrew J. Last will and hereby do move for
6 an order dismissing Plaintiff’s Second Amended Class Action Complaint (ECF No. 88) pursuant
7 to Fed. R. Civ. P. 9(b), 12(b)(6), and the Private Securities Litigation Reform Act.

8 **STATEMENT OF ISSUES TO BE DECIDED (Civil L.R. 7-4(a)(3))**

9 Should the Court dismiss Plaintiff’s claims under Sections 10(b) and 20(a) of the Securities
10 Exchange Act in the Second Amended Complaint for failure to allege with particularity an
11 actionable misstatement or omission, a strong inference of scienter, and loss causation?

12 **MEMORANDUM OF POINTS AND AUTHORITIES**

13 **I. INTRODUCTION**

14 Plaintiff’s Second Amended Complaint (“SAC”) alleges that all of Precigen’s statements
15 during the three-year Class Period discussing the ongoing development of its unique methane
16 bioconversion platform (“MBP”) – a developmental program that was one of Precigen’s many
17 bioengineering ventures – were misleading because the Company failed to disclose details of its
18 lab testing and economic modeling methodologies. Specifically, while the *goal* of the MBP
19 program was to convert methane from inexpensive natural gas into valuable industrial compounds
20 – a goal that was achieved well before the end of the Class Period – and ultimately to achieve
21 commercialization, much of the early laboratory work, which was focused on optimizing the
22 methanotrophic organism underlying the MBP process, used pure methane as a proxy for methane
23 derived from natural gas. Using pure methane allowed Precigen’s scientists to control for the
24 inherent variability in the amount of methane in natural gas samples and, thus, more accurately
25 measure improvements to the methanotrophic organism. In an unadmitted, settled SEC order (the
26 “Order”), *which did not make any assertions of fraud or scienter*, the SEC took the position that
27 although Precigen did not make any affirmative statements about the source of methane, it should
28 have disclosed that it had used pure methane when discussing the results of its early lab tests *in the*

1 *first three quarters of 2017, i.e.*, before it also began successful testing with natural gas.

2 Plaintiff's Complaint relies almost exclusively on the Order as an impermissible and
3 inadequate substitute for the particularized facts required by the PSLRA to establish falsity and a
4 strong inference of scienter. Although the Order (i) is time-limited to the first three quarters of
5 2017, and (ii) did not assert that Precigen made any affirmative representations about the source of
6 methane used in the lab, or about the MBP's commercial prospects, Plaintiff asks the Court to
7 assume that all of Precigen's disclosures throughout the three year Class Period regarding yields
8 and estimates of commercial viability were misleading. Further, although the Individual
9 Defendants and their affiliated entities invested *more than \$180 million* in the Company during the
10 Class Period, Plaintiff asks the Court to infer that Defendants deliberately defrauded investors
11 about the MBP program's results and prospects while watching the value of their own significant
12 investments decline. Finally, Plaintiff asks the Court to infer that the decline in Precigen's stock
13 price over the three-year Class Period was due to the alleged "revelation" that Precigen used pure
14 methane in the lab in one of its many developmental ventures as opposed to the Company's
15 overall deteriorating financial condition borne of funding research for a panoply of promising but
16 not-yet-profitable biotechnology ventures that led to (1) "going concern" warnings, (2) an
17 accumulated deficit approaching \$2 billion, (3) the divestiture of most of Precigen's many non-
18 core, non-health related businesses, and, as a last resort, (4) the suspension of the MBP program
19 just as it was moving towards small-scale commercial production. Precigen's corporate-wide
20 financial deterioration is a far more plausible explanation for Precigen's stock price decline than
21 the statements at issue. Defendants' significant investments, losses, and lack of personal stock
22 sales further refute any inference of scienter. Because Plaintiff's theory of fraud "does not make a
23 whole lot of sense," the SAC should be dismissed without further leave to amend. *Nguyen v.*
24 *Endologix, Inc.*, 962 F.3d 405, 415 (9th Cir. 2020).

25 **II. THE EXHIBITS ARE PROPERLY BEFORE THE COURT**

26 The Exhibits referenced by Defendants are subject to judicial notice (Exs. 1-36), and/or
27 are incorporated by reference into the Complaint (Exs. 2-4, 5-14, 18-24, 26-29, 36). *Khoja v.*
28 *Orexigen Therapeutics, Inc.*, 899 F.3d 988, 999 (9th Cir. 2018). See Birn Decl. ¶¶ 1-36.

1 **III. STATEMENT OF FACTS**

2 Precigen develops platforms of cell and gene therapy designed to enable the production
3 of new and improved biotherapeutics. During the Class Period, it also had a number of non-core
4 initiatives related to food crops, livestock, and energy and chemical products. Ex. 1 at 5; Ex. 2 at
5 6; Ex. 3 at 6; Ex. 4 at 6. One of those initiatives was Precigen’s MBP program. Ex. 1 at 9; Ex. 2
6 at 10-11; Ex. 3 at 10; Ex. 4 at 27. At the center of the MBP program is the methanotroph
7 bacteria, a “unique organism [that] consumes inexpensive methane as its energy source.” Ex. 5 at
8 8; *see also* Ex. 6 at 37. Precigen scientists engineered the naturally-occurring methanotroph’s
9 DNA to enable the bioconversion of methane to produce commercially valuable products, *e.g.*,
10 isobutanol for gasoline blending, 2,3 Butanediol (“2,3 BDO”) for synthetic rubber, and 1,4
11 Butanediol (“1,4 BDO”) for polyester. Ex. 1 at 9; Ex. 2 at 10-11; Ex. 3 at 10; *see also* Ex. 4 at
12 27. The aggregate addressable market for these compounds was estimated to represent over \$100
13 billion annually. *See* Ex. 6 at 38; Ex. 5 at 8; Ex. 7 at 29; Ex. 8 at 6; Ex. 9 at 34; Ex. 2 at 6; Ex. 10
14 at 15; Ex. 11 at 5; Ex. 12 at 18; Ex. 13 at 5.

15 Precigen’s first step in the MBP development process was the optimization of the
16 methanotroph. Ex. 14 at 9; Ex. 10 at 6; Ex. 11 at 6. This involved an iterative process of genetic
17 editing, followed by laboratory testing, leading to further genetic edits designed to achieve DNA
18 sequences that would maximize yields. Ex. 1 at 6; Ex. 2 at 7-8; Ex. 3 at 7. Precigen’s goal was to
19 use methane derived from inexpensive natural gas – which is mostly methane (*see* Ex. 15 at
20 3; Ex. 16 at 1) – as the feedstock to produce the targeted compounds. Early lab testing used pure
21 methane, which allowed Precigen’s scientists to control for variability in the chemical
22 composition of natural gas samples and more accurately assess the effect of improvements to the
23 base methanotrophic organism on end-product yields on an apples-to-apples basis. Plaintiff does
24 not allege that lab testing with pure methane instead of methane derived from natural gas
25 deviated from good scientific practice. After the yields from Precigen’s early lab testing
26 suggested potential commercial viability under its internal financial model, Precigen moved to
27 scale up testing and production-related engineering with natural gas at a larger scale in its pilot
28 plant (Ex. 6 at 37; Ex. 5 at 8; Ex. 8 at 6-7; Ex. 14 at 7) while also continuing testing using both

1 methane and natural gas to further improve the organism. Ex. 7 at 30; Ex. 8 at 6-7; Ex. 9 at 35;
2 Ex. 14 at 7.

3 Plaintiff alleges that ethane in natural gas produces acetate which can inhibit the methane
4 bioconversion process. ¶¶ 26, 52. The SAC, however, pleads no particularized facts disputing
5 that processes to resolve the production of acetate existed and had been successfully used in the
6 industry for decades. Ex. 17 at 1, 38 (“[N]atural gas contains different concentrations of ethane
7 (2.7-20.0%)” which results in “acetate . . . accumul[at]ing in the production plant. *One solution*
8 *to overcome toxic levels. . . is to establish a stable mixed culture with heterotrophic bacteria,*” a
9 process used by Norferm/Dupont). By May 2018, Precigen had improved on these processes,
10 reengineering its proprietary organism to metabolize *both* methane and ethane, resulting in
11 natural gas yields that exceeded those achieved with pure methane. Ex. 18 at 22; Ex. 11 at 6.

12 By the start of the Class Period in May 2017, laboratory yields for two compounds, 2,3
13 BDO and isobutyraldehyde, suggested potential commercial viability if production could be
14 replicated at scale. Ex. 6 at 6; Ex. 5 at 8; ¶ 35. In May, August, and November 2017, Precigen
15 disclosed these yields and announced that it was moving forward with development of 2,3 BDO
16 at a pilot plant (Ex. 6 at 6; Ex. 7 at 30; Ex. 8 at 6-7; Ex. 9 at 34-35; Ex. 14 at 7; ¶¶ 4, 35-36, 117-
17 118, 122-123, 127-131, 133-137), while making clear to investors that “additional yield
18 improvements and scaling milestones must be met” to attain commercial viability. Ex. 6 at 6.

19 After the move to the pilot plant, in November 2018, Precigen *for the first time* specified
20 that it was producing 2,3 BDO “from *natural gas*,” noting it had achieved “roughly 50% of the
21 theoretical target yield.” Ex. 12 at 5 (emphasis added); ¶¶ 152-155; *see also* Ex. 13 at 5. In
22 February 2019, Precigen announced it was “produc[ing] 2,3 BDO from natural gas” at 80% of its
23 target for a small-scale commercial operation. Ex. 19 at 5. Unfortunately, Precigen also
24 announced that decreased revenue and increased research and development expenses across its
25 *many* biotechnology programs had resulted in an accumulated deficit of \$1.3 billion, raising
26 “substantial doubt about its ability to continue as a going concern.” *Id.* at 8; Ex. 20 at 5; Ex. 3 at
27 25. By the following year, the corporate deficit had increased to \$1.7 billion. Ex. 4 at 30.

28 In January 2020, Precigen announced that to preserve cash it would focus on its core

1 health care initiatives and had divested all but two of its most promising non-health ventures
2 (including the MBP program). *Id.* at 7, 26-29. In May 2020, as a result of the pandemic and the
3 challenging state of the energy sector, Precigen announced “the difficult but necessary decision”
4 to suspend the MBP program to further minimize expense, later taking an impairment charge. ¶
5 86 (Ex. 21 at 5); ¶ 88 (Ex. 22 at 6; Ex. 23 at 28).

6 In September 2020, Precigen entered into a settlement Order with the SEC concerning
7 three 8-Ks filed in May, August, and November 2017 (Exs. 6, 7, and 9) (the “2017 8-Ks”)
8 reporting 2,3 BDO yields. Ex. 24. The SEC believed the 2017 8-Ks’ disclosures did not
9 sufficiently identify the source of methane used in lab testing during the first three quarters of
10 2017 before testing began with natural gas. *Id.* at 2. By its terms, the Order: (1) applies “[s]olely
11 for the purpose of [SEC] proceedings;” (2) notes Precigen did not admit any of the SEC’s
12 assertions; (3) relates only to statements about 2,3 BDO yields in the 2017 8-Ks; (4) does not
13 assert Precigen made affirmative representations about its methane source or methods; and (5)
14 makes no allegations of fraud as to any statement nor scienter as to any Individual Defendant,
15 none of whom are mentioned. *Id.*

16 **IV. ARGUMENT**

17 Plaintiff claims that all of Defendants’ statements about the MBP program throughout the
18 more-than-three-year Class Period were misleading (and made with scienter) because Defendants
19 did not disclose that: (1) MBP yields were achieved with pure methane, not methane from
20 natural gas, (2) yields achieved with natural gas were lower than with pure methane, and (3)
21 none of the compounds derived from the MBP program were “in-the-money,” i.e., potentially
22 commercially viable if the cost of pure methane was used in the calculation and/or unless
23 Precigen “cherry-picked” data inputs from different experiments rather than overall testing
24 results. ¶¶ 40, 60-61, 116, 124, 126, 132, 138, 140, 146, 151, 157, 159, 162. Plaintiff also claims
25 Precigen had a duty to disclose the SEC investigation earlier than it did. ¶ 83. Plaintiff’s
26 allegations fail to meet the PSLRA’s heightened pleading standards and should be dismissed.

27
28

1 **A. The Order Does Not Establish Falsity or Scienter**

2 Plaintiff May Not Rely on the Order to Establish Facts: Unadmitted “[s]tatements made
3 by the SEC in settlement documents are . . . ‘untested assertions by litigants,’” (*In re Facebook,*
4 *Inc. Sec. Litig.*, 477 F. Supp. 3d 980, 1017 n.4 (N.D. Cal. 2020) (citation omitted)), “are not
5 ‘findings’ upon which Plaintiffs may rely,” (*Cho v. UCBH Holdings, Inc.*, 890 F. Supp. 2d 1190,
6 1203 (N.D. Cal. 2012)), and are “not sufficient to meet the pleading requirements of the
7 PSLRA.” *Glazer Capital Mgmt., LP v. Magistri*, 549 F.3d 736, 748-49 (9th Cir. 2008).

8 The Scope of the Order is Limited: The Order relates only to the 2017 8-Ks (not any other
9 statements) and only to stated “yields for 2,3 BDO” (not any other target compounds), and only
10 claims that the source of the methane used to obtain the 2,3 BDO yields should have been made
11 clear, while not asserting that any affirmative representations about the source of methane were
12 made or disputing the accuracy of the actual yields themselves. Ex. 24 at 2-5. Neither the Order
13 nor Plaintiff dispute that Precigen successfully tested MBP on natural gas in and after mid-2017
14 and accurately reported test yields in all of 2017 and after, specifying those based on natural gas.

15 The Order and the Cited Disclosures Contradict Plaintiff’s Claims: The Order reflects
16 that “[a]t the time of the laboratory experiments with pure methane as a feedstock” Precigen’s
17 “scientists were working on methods to achieve similar yields/titers with natural gas and, while
18 they were optimistic, they had not done so *at the time [of] the relevant disclosures,*” *i.e.*, when
19 the 2017 8-Ks were filed in May, August, and November 2017. Ex. 24 at 2, 3, 5 (emphasis
20 added). The clear implication of this time-limited recital, and the fact that the SEC did not
21 challenge any later disclosures despite its then-ongoing investigation, is that Precigen
22 *subsequently did* achieve similar yields/titers with natural gas as its later disclosures confirm. By
23 November 2017 (not coincidentally the end-date of the disclosures challenged in the Order),
24 Precigen had begun testing 2,3 BDO in its pilot plant *using natural gas*. Ex. 8 at 6-7; Ex. 14 at 7.
25 In November 2018, Precigen announced that 2,3 BDO yields “from natural gas” reached 50% of
26 its target yield for small-scale commercialization. Ex. 12 at 5; ¶¶ 152-155; *see also* Ex. 13 at 5.
27 By February 2019, yields “from natural gas” had increased to 80% of that goal, prompting site
28 selection and design for such a plant. ¶ 158 (citing Ex. 19 at 5).

1 The SAC provides *no* factual allegations contradicting these achievements, subsequent to
 2 the period addressed in the Order, *with natural gas*. Merely “repeat[ing] allegations related to
 3 events occurring earlier in time [in a bioconversion development process] do[es] not provide
 4 ‘specific facts demonstrating that the [subsequent] statements . . . [as development progressed]
 5 were false or misleading when made.’” *Browning v. Amyris, Inc.*, 2014 WL 1285175, at *11
 6 (N.D. Cal. Mar. 24, 2014). Moreover, neither the Order nor the SAC point to any affirmative
 7 representations claiming that yields were based on natural gas *prior to November 2018*, even
 8 though testing with natural gas in the pilot facility had begun a year before.

9 *The Order Made No Assertions of Fraud or Scienter:* The Order does not assert that the
 10 2017 8-Ks (much less any other statements) were fraudulent or that any Individual Defendant
 11 acted with scienter. The Order only alleges non-scienter-based violations of Section 13(a) of the
 12 Exchange Act (Ex. 24 at 2). *Ponce v. SEC*, 345 F.3d 722, 737 n.10 (9th Cir. 2003). Thus, the
 13 Order’s recitals, which do not meet the PSLRA’s pleading requirements (*Glazer*, 549 F.3d at
 14 748), cannot establish scienter or fraud.

15 **B. The Ninth Circuit Recently Rejected Plaintiff’s Fraud-by-Implication Theory**

16 At most, the Order suggests that the 2017 8-Ks – which, again, made *no* affirmative
 17 representations about the source of methane used in lab testing – could have led investors to fill
 18 in the blanks and assume that the accurately stated yields were achieved using natural gas. The
 19 Ninth Circuit has rejected such “misleading-by-implication” theories as insufficient to state a
 20 claim for securities fraud. *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1187, 1193 (9th Cir. 2021).

21 In *Tesla*, plaintiffs claimed they were misled to believe that Tesla had begun
 22 manufacturing its new Model 3 on an automated assembly line – its ultimate goal – when, in
 23 fact, during the start-up phase of production, cars were still being “banged out by hand.” *Id.* The
 24 Ninth Circuit rejected the assertion that Elon Musk’s accurate statements that Tesla had installed
 25 “manufacturing equipment” and was delivering “production” cars falsely implied that it had
 26 “begun installation of *automated* equipment.” *Id.* The Court noted: “Plaintiffs’ brief rewrites th[e]
 27 challenged] statement as if it asserted that Tesla had ‘begun installation of automated
 28 equipment in the first quarter.’ . . . But that is not what the statement says—it simply confirms

1 that some unspecified ‘manufacturing’ equipment had been installed at the Tesla facilities, and
2 the complaint does not plead any facts to establish that *that* representation was false.” *Id.*; *see*
3 *also id.* at 1194. Because the *Tesla* plaintiffs did not plead facts showing that *no* “manufacturing
4 equipment” had been installed, that cars had not been produced and delivered, or that Tesla’s
5 production goals were known to be impossible, the Ninth Circuit affirmed dismissal for failure to
6 plead facts demonstrating “‘the reason or reasons why’” Musk’s literally true and accurate
7 statements were false and misleading as the PSLRA requires. *Id.* at 1193.

8 This case is just like *Tesla*. Here, Plaintiff does not dispute that the MBP platform
9 converted methane to 2,3 BDO and other products, that the stated yields were accurate, or that
10 applying those yields to natural gas prices put the compounds “in the money,” *i.e.*, produced
11 positive gross margins making them potentially commercially viable. *E.g.*, ¶ 118; *see also* ¶ 36;
12 Ex. 6 at 6. Instead, as in *Tesla*, Plaintiff claims that investors may have made assumptions about
13 the *methods* Defendants used to achieve the accurately stated outputs, *i.e.*, that Tesla’s cars were
14 being made on an automated production line and that Precigen’s laboratory yields were achieved
15 with methane derived from natural gas. However, just as the plaintiffs in *Tesla* could not point to
16 any affirmative statement that production was already automated, Plaintiff here does not and
17 cannot contend that Precigen ever affirmatively represented that the methane used in its lab was
18 derived from natural gas – except by mischaracterizing Defendants’ actual statements. Thus,
19 while Plaintiff alleges the 2017 8-Ks state that the MBP program had achieved “the profitable
20 use of low cost natural gas,” (¶¶ 36, 119) a review of the attached presentations shows that “that
21 is not what the statement says.” *Tesla*, 985 F.3d at 1193. Instead, Precigen only claimed that
22 MBP technology “enables the profitable use of low cost natural gas,” not that natural gas was
23 used in the lab. Similarly, Precigen only stated that extrapolating from these laboratory “yield
24 level[s] produces a positive ‘in the money’ gross margin based on current natural gas and
25 product prices,” caveating those forecasts with cautions that “additional yield improvements and
26 scaling milestones must be met” (Ex. 6 at 6) and that “scientific . . . and scale-up risks . . . could
27 create delays . . . and . . . alter our economic model” (Ex. 5 at 8), *not* that the compounds were
28 already “in the money” (¶¶ 118, 119). Because Precigen made no affirmative representation

1 about the inputs or methods, scientific or economic, used to make this forecast about potential
 2 commercial viability, it had no duty to disclose such details. *City of Sunrise Firefighters’*
 3 *Pension Fund v. Oracle Corp.*, 2021 WL 1091891, at *16, *19 (N.D. Cal. Mar. 22, 2021).

4 These principles are particularly applicable in the context of scientific experimentation
 5 because “researchers may well differ with respect to what constitutes acceptable testing
 6 procedures, as well as how best to interpret data.” *Padnes v. Scios Nova Inc.*, 1996 WL 539711,
 7 at *5 (N.D. Cal. Sept. 18, 1996), *cited with approval in In re Rigel Pharm., Inc. Sec. Litig.*, 697
 8 F.3d 869, 879 (9th Cir. 2012). Thus, “[t]he securities laws do not ‘require that companies who
 9 report information from [scientific research] include exhaustive disclosures of procedures used,
 10 including alternatives that were not utilized and various opinions with respect to the effects of
 11 these choices on the interpretation of the outcome data.” *In re Nuvelo, Inc., Sec. Litig.*, 2008 WL
 12 5114325, at *11 (N.D. Cal. Dec. 4, 2008). Instead, where, as here, “‘Plaintiff[s] do[] not allege
 13 that Defendants misrepresented their . . . methodology, analysis, and conclusions, but instead
 14 criticize[] . . . [the] methodology employed by Defendants, [as being at odds with what investors
 15 may have “assumed,” they do] not adequately plead falsity with respect to [the reported
 16 scientific] results.’” *Mulquin v. Nektar Therapeutics*, 510 F. Supp. 3d 854, 860, 868 (N.D. Cal.
 17 2020) (quoting *Rigel*, 697 F.3d at 879).

18 In sum, the fact that Precigen did not *affirmatively claim* that its lab testing used methane
 19 derived from natural gas until November 2018, well after such testing began, and the fact that
 20 Plaintiff does not allege that the stated *yields* from such testing were false, “poses an impassable
 21 barrier to Plaintiff.” *Oracle*, 2021 WL 1091891, at *19.

22 **C. The CWs Do Not Show That Any Statement Was False or Made with Scienter**

23 Other than the Order, Plaintiff offers only self-described “backroom chatter” and
 24 speculation from former employees of the MBP division – researchers, engineers, and scientists
 25 – none of whom reported to and only one whom even allegedly once spoke to any of the
 26 Individual Defendants. ¶¶ 49, 51, 53, 57, 68, 73, 75. None of the CWs claim knowledge of or
 27 involvement with the challenged disclosures, the “techno-economic model” allegedly used to
 28 assess commercial viability, or any Defendant’s state of mind. Thus, none of CW allegations

1 “pass the two hurdles [necessary] to satisfy the PSLRA pleading requirements:” (1) none are
2 “described with sufficient particularity to establish their reliability and personal knowledge” and
3 (2) their reports are not “indicative of scienter.” *Oracle*, 2021 WL 1091891, at *3 (citing *Zucco*
4 *Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 995 (9th Cir. 2009)).

5 *First*, none of the CWs claim to have had *any* interaction with Last or Sterling; two
6 merely allege being at “town hall” meetings with Walsh which Kirk also “sporadically” attended
7 (¶¶ 66, 68, 70-72, 74 & n.4), *but* neither provide any details as to the dates or content of these
8 meetings. Mere attendance at meetings or generalized allegations that developmental
9 “challenges” were “very apparent and discussed throughout the [MBP] organization” (¶¶ 47, 55,
10 75), or reported to a divisional supervisor (Yeh) (¶¶ 48, 50-51, 53, 55-58, 64-65, 67, 73-74)
11 amount to no more than speculation about what the Individual Defendants might have known –
12 which cannot satisfy the PSLRA’s rigorous standard for pleading scienter. *Zucco*, 552 F.3d at
13 998; *Iron Workers Local 580 Joint Funds v. NVIDIA Corp.*, 522 F. Supp. 3d 660, 675-66 (N.D.
14 Cal. 2021); *In re Pivotal Sec. Litig.*, 2020 WL 4193384, at *16–17 (N.D. Cal. July 21, 2020).
15 Here, the only alleged direct communication with any Defendant *undermines* any inference of
16 scienter: CW4 reports that Kirk “responded approvingly” to CW4’s “recommend[ation] that the
17 Company invest in a 20,000-liter facility” (¶ 66) suggesting that both believed the MBP
18 program’s success justified progression to, and significant investment in, a commercial plant.

19 *Second*, the CW allegations are not “indicative of scienter” because none of the CWs
20 point to any specific data that was at odds with any disclosure. ¶¶ 58-59, 62, 64, 69; *NVIDIA*,
21 522 F. Supp. 3d at 675-66. Mere access to data from the lab information system or the techno-
22 economic model or otherwise, (and, here, the allegations of “access” are not specific to any
23 individual) (¶¶ 23, 64) creates no inference of scienter. *NVIDIA*, 522 F. Supp. 3d at 678. Instead,
24 Plaintiff must “tie . . . *specific* [data]” “to *particular* statements so as to plausibly show that the
25 [*specific*] Defendant who made each *specified* statement knowingly or recklessly spoke falsely.”
26 *Id.* at 674-75 (emphasis added); *see also Zucco*, 552 F.3d at 998. None of these requisite
27 specifics are pled. Absent specific facts at odds with specific disclosures, the fact that Walsh was
28 a scientist who “led” the MBP program (¶ 21), spoke about its results (¶¶ 36, 150), and allegedly

1 kept Kirk and the other defendants “regularly apprised,” (¶ 95) does not give rise to a strong
2 inference of scienter. *In re AnaptysBio, Inc. Sec. Litig.*, 2021 WL 4267413, at *10 (S.D. Cal.
3 Sept. 20, 2021) (no inference of scienter based on defendants’ status and scientific expertise).

4 Instead of specific data, the CWs provide only broad allegations of “challenges,”
5 “roadblocks,” “difficulties” and “struggles” (¶¶ 50, 52, 56, 65, 71), which are insufficiently
6 detailed, untethered in time, and lump together every issue affecting every compound over the
7 course of a complex multi-year development process, ignoring that such issues were overcome
8 and, as Precigen repeatedly disclosed, often affected compounds other than the target product,
9 2,3 BDO. Ex. 25 at 9, 12 (“promiscuous enzyme” delayed isobutanol development while 2,3
10 BDO progressed); *see also* Ex. 5 at 8, 13, 17; Ex. 8 at 6, 16; Ex. 14 at 7, 9; Ex. 26 at 15; Ex. 27
11 at 6; ¶ 142; *City of Sunrise Firefighters’ Pension Fund v. Oracle Corp.*, 2019 WL 6877195, at
12 *42 (N.D. Cal. Dec. 17, 2019) (“CW reports must be specific in their time references” and
13 sufficiently detailed “to support that each alleged misstatement was false when made.”). The few
14 seemingly specific allegations about “challenges” merely describe issues endemic to the
15 bioconversion process. The “challenge” described by CW1 – “get[ting] the relevant bacteria to
16 respond to natural gas the same way they responded to pure methane” (¶ 50) – merely describes
17 the very purpose of the *successful* natural gas testing, which ultimately produced *increased*
18 yields, and began shortly after CW1 left the Company. *Endologix*, 962 F.3d at 416 (rejecting
19 allegations from CW who left shortly after class period). Similarly, CW3’s observation that “the
20 use of natural gas as a feedstock in the bioconversion process created acetate, which materially
21 reduced the feedstock’s productivity,” (¶ 55) was well known to any industrial biochemist using
22 natural gas feedstock, as was the decades-old metabolic solution to neutralize the ethane which
23 resulted in acetate. Ex. 17 at 1, 38. Indeed, Precigen developed a more elegant process,
24 engineering its own methanotroph to metabolize both methane and ethane, thereby eliminating
25 the deleterious by-production of acetate and actually *increasing* yields as compared to
26 established methods long before CW3 joined the Company in mid-2019. ¶ 53; *see* Ex. 18 at 22;
27 Ex. 11 at 6. The CWs offer no particularized facts disputing that Precigen had solutions for these
28 challenges. Thus, to the extent these or other “challenges” existed, Plaintiff fails to plead facts

1 demonstrating scienter, *i.e.*, that any Defendant did not believe that they could be overcome.
2 *Tesla*, 985 F.3d at 1194 (rejecting CW allegations that start up production issues could not be
3 overcome where no facts alleged to show Musk accepted the CW’s views); *Hampton v. Aqua*
4 *Metals, Inc.*, 2020 WL 6710096, at *14 (N.D. Cal. Nov. 16, 2020) (CW allegations “do[] not
5 provide any facts concerning [the defendants’] belief as to whether issues [in a new production
6 process], to the extent they existed, would be material or significant.”).

7 Similar deficiencies afflict the CWs’ assertions about the MBP program’s alleged failure
8 to meet internal target rates or goals. CW2 ¶ 52; CW 3 ¶ 55; CW5 ¶¶ 69, 71; CW6 ¶ 74. The
9 “[f]ederal securities laws do not punish companies for failing to achieve their targets[,]”
10 particularly where, as here, Plaintiff does not allege that internal goals or targets were ever
11 shared with investors. *Wochos v. Tesla, Inc.*, 2019 WL 1332395, at *5 (N.D. Cal. Mar. 25, 2019),
12 *aff’d*, 985 F.3d 1180 (9th Cir. 2021); *see also Amyris*, 2014 WL 1285175, at *10-11. Nor do the
13 CWs’ assertions that commercialization was not achieved (CW3 ¶ 56) or was years away (CW5
14 ¶ 75) – which are not tied to any particular “challenge” – demonstrate scienter or fraud. It is
15 undisputed that Precigen ultimately achieved yields using natural gas that exceeded those
16 achieved with pure methane (Ex. 11 at 6; Ex. 10 at 15; Ex. 13 at 5; Ex. 12 at 5; Ex. 19 at 5) and
17 that the MBP program was proceeding towards commercialization (Ex. 12 at 5; Ex. 13 at 5; Ex.
18 19 at 5). The CWs’ views about production and commercialization timelines or prospects “fail[s]
19 to plead facts showing that Defendants adopted the . . . timeline for production [or
20 commercialization] on which these employees’ pessimism was based,” or that they “*shared th[e*
21 *employees’] gloomy view*” that production or commercialization “goal[s] were *impossible* to
22 achieve.” *Tesla*, 985 F.3d at 1194. The fact, viewed in hindsight, “[t]hat the Company did not
23 ultimately complete the transition to commercialization or successfully commence commercial
24 production . . . does not, by itself, make any of its [earlier] statements that it was transitioning to
25 commercialization false or misleading.” *Aqua Metals*, 2020 WL 6710096, at *10.

26 Finally, CW4’s challenge to Precigen’s opinion that 2,3 BDO was “in the money” is
27 based solely on non-expert speculation. ¶ 63. CW4 was an engineer whose work focused on
28 laboratory testing and pilot plant processes. ¶ 57. CW4 does not claim to have had any

1 responsibility for the techno-economic model Precigen used to assess commercial viability.
2 Rather he alleges that Brian Yeh “develop[ed] and maintain[ed] the company’s techno-economic
3 models.” ¶ 58. Although CW4 opines that Defendants’ “in the money” statements were false (¶
4 63) his opinion is based entirely on assertions that are contrary to the very SEC Order upon
5 which Plaintiff relies, are unsubstantiated and well outside his area of expertise, and far too
6 conclusory and ambiguous to satisfy the PSLRA’s heightened pleading standard. First, CW4’s
7 opinion regarding the “in the money” statements is based on his assertion that (1) “yield” and
8 “titer” were different metrics (¶ 59) and (2) the Company must have “cherry-picked” data from
9 separate experiments to obtain positive results because “titer” and “productivity” (*i.e.*, the time
10 required to make a given amount of product) “fight each other.” ¶¶ 60-61. CW4’s first assertion
11 is inconsistent with the SEC Order, on which Plaintiff otherwise relies, which concluded that
12 “yields” as publicly reported by Precigen and “titers” were the same metric. Ex. 24 ¶ 5 (“yields
13 were a measure of productivity referred to internally as ‘titers.’”). And, absent *facts* showing that
14 productivity varied in the experiments that were the basis for the reported yields, CW4’s second
15 assertion that the results must have been cherry-picked is pure speculation. CW4’s opinion is
16 also based on his very own definition of the phrase “in the money” requiring an “overall level of
17 profitability” requiring an internal rate of return of 30% (¶¶ 58-60), ignoring that the Company
18 clearly defined the phrase simply as “positive gross margins.” Ex. 6 at 6; ¶ 118. Finally, CW4’s
19 opinion is based on his assertion that the Company never achieved “satisfactory” or “positive”
20 results, but provides no detail or explanation of what those vague and conclusory terms mean. ¶¶
21 59-60. Other courts have rejected almost identical CW allegations, *i.e.*, that management must
22 have been “aware that it would not be able to translate peak yields . . . produced in lab settings,
23 to stable and reliable production at factory scale” and “cherry picked the very best available data
24 from tests at every step of the process,” finding that such conclusory allegations “do not ‘provide
25 an adequate basis’ for CW’s beliefs” and, instead, “demonstrate that the confidential witnesses
26 are not reliable.” *Amyris*, 2014 WL 1285175, at *18 (quoting *Zucco*, 552 F.3d at 995-96). In any
27 event, internal disagreements about the methodologies underlying reported scientific results do
28 not demonstrate scienter. *Nektar*, 510 F. Supp. 3d at 866. Moreover, while CW4 claims to have

1 expressed concerns to Yeh that Precigen’s “in the money” statements were “materially
2 misleading,” there are no allegations that Yeh agreed with or relayed CW4’s opinion to any of
3 the Individual Defendants. ¶ 65. *Tesla*, 985 F.3d at 1194.

4 Because none of the CW allegations support falsity or scienter, they must be rejected.

5 **D. Many of the Challenged Statements Are Non-Actionable Puffery, Opinions and/or**
6 **Forward-Looking Statements Immunized by the PSLRA’s Safe Harbor**

7 1. Statements of Pride and Optimism are Immaterial as a Matter of Law

8 Defendants’ vague statements of pride and optimism, describing its MBP program as
9 achieving “breakthrough” (¶ 39) “milestone[s]” (¶ 150), believed to represent “the most valuable
10 biotechnology in history” (¶ 101), or using general superlatives like “solid,” “robust,” “a leader,”
11 “significant,” “major,” “excit[ing],” or “high-value” to describe the MBP program’s progress, its
12 products’ potential, or its partnership prospects (¶¶ 29-31, 36, 39, 41-42, 97, 100-101, 122, 125,
13 128, 130-31, 137, 139, 142, 144-145, 150, 153) are “textbook examples of non-actionable
14 puffery and corporate optimism” (*Welgus v. TriNet Grp., Inc.*, 2017 WL 6466264, at *11 (N.D.
15 Cal. Dec. 18, 2017), *aff’d*, 765 F. App’x 239 (9th Cir. 2019) (citations omitted)) which “are
16 subjective and unverifiable assessments and therefore, non-actionable.” *Oracle*, 2019 WL
17 6877195, at *9; *see also In re Intrexon Corp. Sec. Litig.*, 2017 WL 732952, at *3 (N.D. Cal. Feb.
18 24, 2017) (“we believe we are a leader in the field of synthetic biology”); *Aqua Metals*, 2020 WL
19 6710096, at *13 (“breakthrough technology,” “major milestone”); *Amyris*, 2014 WL 1285175, at
20 *9-10 (“landmark” bioconversion process); *Hong v. Extreme Networks, Inc.*, 2017 WL 1508991,
21 at *12-13 (N.D. Cal. Apr. 27, 2017) (“significant value,” “productive discussions,” and
22 “progress” with partners). Such “optimistic, subjective assessment[s] . . . [do not] amount[] to a
23 securities violation” because “investors do not rely on puffery when making investment
24 decisions.” *Oracle*, 2021 WL 1091891, at *11.

25 2. Forward-Looking Statements Protected by the PSLRA Safe Harbor

26 Plaintiff also challenges a host of optimistic forward-looking statements which are
27 couched in caution and, thus, immunized from liability under the PSLRA’s safe harbor. *Tesla*,

28

1 985 F.3d at 1189-92. All of Precigen’s plans and projections for commercializing products using
2 its MBP platform (¶¶ 31, 36, 41, 77, 98, 118, 122, 128, 130-131, 135-137, 142, 145, 148, 150,
3 153, 155, 158) are “unquestionably . . . ‘forward-looking statement[s].’” *Id.* at 1192; *Aqua*
4 *Metals*, 2020 WL 6710096, at *7. *Tesla* also makes clear that statements describing Precigen’s
5 product development and production goals as “on track” (¶¶ 31, 98, 142, 148, 153, 155, 158) and
6 projected to be “in the money” (¶¶ 31, 36, 41, 98, 118, 119, 122, 128, 130-131, 135, 137, 145,
7 150) are also forward-looking because they reflect “an implicit assertion that the goal is
8 achievable based on current circumstances.” *Tesla*, 985 F.3d at 1192. Moreover, as *Tesla* makes
9 plain, a forward-looking statement concerning future production goals is not actionable merely
10 because Plaintiff alleges that it rests on “unlikely” “subsidiary premises,” *i.e.*, that necessary
11 process improvements – such as increased yields, titers, productivity, and scalability – can be
12 achieved in the future. *Id.* That is because “‘the assumptions underlying or relating’ to a declared
13 objective” also fall within the safe harbor. *Id.* Finally, the safe harbor also protects statements
14 estimating addressable markets for the end-products Precigen hoped to produce (¶¶ 39, 101, 120,
15 121, 125, 139, 149, 160). *Oracle*, 2021 WL 1091891, at *13 (“The size of these markets are
16 enormous, and we think we’ll be able to ride that horse, pursue that organic growth and meet our
17 targets.”); *In re Cloudera, Inc. Sec. Litig.*, 2021 WL 2115303, at *18 (N.D. Cal. May 25, 2021)
18 (merger would “enlarge addressable market”); *Police & Fire Ret. Sys. v. Axogen, Inc.*, 2021 WL
19 1060182, at *3-4 (M.D. Fla. Mar. 19, 2021) (addressable market estimates within safe harbor).

20 Precigen’s forward-looking statements were identified as such and were accompanied by
21 specific cautionary language, warning investors, *inter alia*, that the MBP program was in the
22 “early stages” of development and “may not be able to develop and commercialize” its
23 technologies, which “may not perform as expected when applied at commercial scale.” Ex. 1 at
24 4, 30, 32; Ex. 2 at 4, 24, 40-41; Ex. 3 at 4, 25, 42-43; Ex. 4 at 4, 30-32; Ex. 28 at 8; *see also, e.g.*,
25 Ex. 6 at 6 (“additional yield improvements and scaling milestones must be met”); Ex. 5 at 8
26 (“possible scale-up risks . . . could create delays that push out our time lines and could alter our
27 economic model”); Ex. 1 at 47 (we “may never achieve or maintain profitability”); Ex. 2 at 24
28 (same); Ex. 3 at 25 (same); Ex. 4 at 30 (same). Because these warnings informed investors of

1 factors that might prevent the successful commercialization of products developed in the MBP
 2 program, Precigen’s forward-looking statements are exempt from liability. *Aqua Metals*, 2020
 3 WL 6710096, at *6-7 (warnings of risks “associated with the development of a business model
 4 that is untried and unproven” and that “there can be no assurance that we will be able to produce
 5 . . . in commercial quantities at a cost of production that will provide us with an adequate profit
 6 margin” or “replicate the process . . . on a large commercial scale” sufficient under the PSLRA
 7 safe harbor (emphasis omitted)); *Amyris*, 2014 WL 1285175, at *4 (same). As the *Tesla* Court
 8 stated, where such cautions are provided, “plaintiff cannot defeat that invocation of [the] safe
 9 harbor merely by alleging . . . that the company knew that the announced forward-looking
 10 objective was unlikely to be achieved.” *Tesla*, 985 F.3d at 1190.

11 3. Precigen’s Optimistic Opinions are Non-Actionable

12 Many of the challenged statements are non-actionable opinions expressing Precigen’s
 13 “belief” or “estimates” about the results and commercial implications of its laboratory and pilot
 14 plant testing. *E.g.*, ¶¶ 31, 39, 98, 101, 120-121, 125, 130, 137, 139, 144, 149, 160. “Courts have
 15 repeatedly held ‘publicly stated interpretations of the results of [scientific] studies’ to be
 16 ‘opinions’ because ‘[r]easonable persons may disagree over how to analyze data and interpret
 17 results, and neither lends itself to objective conclusions.’” *E.g.*, *In re Restoration Robotics, Inc.*
 18 *Sec. Litig.*, 417 F. Supp. 3d 1242, 1260 (N.D. Cal. 2019) (citation omitted).

19 “[P]ure statement[s] of opinion’ [are] generally not actionable.” *Tesla*, 985 F.3d at 1196
 20 (citation omitted). Where, as here, Plaintiff does not plead particularized facts demonstrating
 21 either that: (1) “the speaker did not hold the belief she professed” (not merely that the belief was
 22 unreasonable or even “irrational”) or that (2) a “supporting fact” “for an opinion statement is . . .
 23 untrue,” it can only state a claim based on an opinion by showing that omitted “facts going to the
 24 basis” of the opinion render it “misleading [when] reading the statement fairly and in context.”
 25 *City of Dearborn Heights Act 345 Police & Fire Ret. Syst. v. Align Tech., Inc.*, 856 F.3d 605,
 26 615-16 (9th Cir. 2017) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension*
 27 *Fund*, 575 U.S. 175, 192-94 (2015)). Challenging opinions under *Align’s* third “omissions”
 28 prong, as Plaintiff attempts here, is “no small task” because “liability is not necessarily

1 established by demonstrating that ‘an issuer knows, but fails to disclose, some fact cutting the
 2 other way.’” *Align*, 856 F.3d at 615-16. That is particularly true where, as here, (1) the opinion is
 3 caveated with disclaimers and cautions, and (2) there are “positive and mitigating [factors]
 4 that [the Company] could have found to either balance or outweigh the [omitted] events and
 5 circumstances” which are alleged to render the opinion misleading. *Id.* at 616, 618.

6 Here, none of Precigen’s opinions about the actual and potential successes of the MBP
 7 program or the commercial viability of its products were rendered false or misleading by virtue
 8 of the alleged omissions – *i.e.*, that lab testing yields were achieved with pure methane and the
 9 Company’s “in the money” opinions were as-yet unrealized extrapolations. That is because, as
 10 shown, Precigen (1) (correctly) believed that there were solutions to the challenges involved in
 11 achieving similar yields using natural gas at commercial scale (*Align*’s “positive and mitigating”
 12 factors) and (2) regularly warned investors of potential risks as well as actual setbacks as they
 13 occurred (*Align*’s directive that opinions be read in context). *Supra*, at 11 n.6 (disclosing the
 14 “promiscuous enzyme” issue with isobutanol), 15-16 (risk factors). In such circumstances,
 15 opinions, like Precigen’s, that “‘great progress’ was being made” are not actionable unless,
 16 unlike here, there had been “no progress at all.” *Tesla*, 985 F.3d at 1196; *accord id.* at 1191-94
 17 (forward-looking optimistic opinions about aggressive production goals not actionable where
 18 their achievement was not shown to be “impossible” and company warned about the potential
 19 risks and actual setbacks that made success unlikely; applying the safe harbor).

20 **E. Precigen’s Disclosures Concerning the SEC Investigation Were Not Misleading**

21 Plaintiff also claims that Precigen’s statements in its November 2018 Q3 10-Q and FY
 22 2018 10-K that it “may become subject to . . . governmental investigations from time to time”
 23 were misleading because the SEC investigation leading to the Order began in October 2018.
 24 ¶¶ 45, 116, 156, 157, 161, 162. However, in addition to disclosing that such investigations “may”
 25 occur, the Q3 2018 10-Q also categorically stated that “[f]rom time to time, we *are* involved in
 26 litigation or legal matters, including governmental investigations.” Ex. 29 at 61 (emphasis
 27 added). There is no duty to disclose a government investigation absent “some affirmative
 28 statement or omission by [an issuer] that suggested it was *not* under any regulatory scrutiny.”

1 *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1071 (9th Cir. 2008). Statements
 2 that a company is (not just *may* be) involved in regulatory matters from “time to time” or
 3 “periodically” do not give “reasonable investor[s] the impression that [it] was not actively
 4 involved in investigations.” *In re Inv. Tech. Grp. Sec. Litig.*, 251 F. Supp. 3d 596, 616 (S.D.N.Y.
 5 2017); *In re Lions Gate Entm’t Corp. Sec. Litig.*, 165 F. Supp. 3d 1, 17 (S.D.N.Y. 2016).

6 **F. Defendants Cannot Be Held Liable for Statements They Did Not Make**

7 A defendant can only be held liable under Section 10(b) if he or she “make[s]” a
 8 challenged statement, *i.e.*, if he has “ultimate authority” over the statement. *Janus Capital Grp.,*
 9 *Inc. v. First Derivative Traders*, 564 U.S. 135, 141-42 (2011). Thus, none of the Individual
 10 Defendants can be liable for (1) statements made after they left the Company; (2) statements in
 11 SEC filings or press releases which they did not sign and are not alleged to have prepared; or (3)
 12 any other Defendant’s oral statements. *Aqua Metals*, 2020 WL 6710096, at *17-18 (no liability
 13 for others’ statements in earnings calls or press releases arises from mere attendance at calls).
 14 Notably, neither Defendant Last, who left in December 2017 (ten months before the SEC began
 15 its investigation) (¶ 22) and made no statements after November 2017 (¶¶ 41, 137) nor
 16 Defendant Walsh, who left in November 2019 (¶ 21) and only made two challenged statements,
 17 during the May 10, 2017 and August 9, 2018 earnings calls (¶¶ 36, 150), is alleged to have
 18 signed or prepared any SEC filings or press releases.

19 **G. Plaintiff Fails to Establish the Requisite “Strong Inference” of Scienter**

20 To meet the PSLRA’s “high burden” for pleading the requisite “strong inference” of
 21 scienter, “a complaint must allege that the defendant made false or misleading statements” and
 22 “state specific facts indicating no less than a degree of recklessness that strongly suggests actual
 23 intent.” *Prodanova v. H.C. Wainwright & Co.*, 993 F.3d 1097, 1106-08 (9th Cir. 2021). As in
 24 *Prodanova*, the Complaint here fails to “meet[] this high burden.” *Id.*

25 As a threshold matter, because “Plaintiff[] ha[s] not adequately pled that Defendants’
 26 [statements] were actually false or misleading. . . . it follows that Plaintiff[] ha[s] not adequately
 27 pled facts from which one can infer that Defendants knew their statements [were] false or
 28 misleading.” *City of Royal Oak Ret. Sys. v. Juniper Networks, Inc.*, 880 F. Supp. 2d 1045, 1068

1 (N.D. Cal. 2012). As also shown, neither the Order nor the CWs provide facts probative of any
 2 Individual Defendants’ state of mind in connection with the challenged disclosures and there are
 3 no admissions, internal documents, or witnessed meetings to fill the void. As discussed below,
 4 Plaintiff’s conclusory “core operations” theory (¶ 101), unsupported by any corroborating, much
 5 less particularized facts, fails. Instead, Precigen’s continued investment in the MBP program, the
 6 Individual Defendants’ significant additional investments in the Company, and the cautionary
 7 language that accompanied the challenged statements, support a far more compelling inference
 8 of innocence, not scienter or fraud.

9 1. Plaintiff Fails to Plead Scienter Under The Core Operations Theory

10 Where, as here, Plaintiff relies on the “core operations” theory of scienter, which “infers
 11 that facts critical to a business’s ‘core operations’ . . . are known to a company’s key officers”
 12 “but does not [provide] additional detailed allegations about the defendants’ actual exposure to
 13 information, it will usually fall short of the PSLRA standard.” *S. Ferry LP, No. 2 v. Killinger*,
 14 542 F.3d 776, 783-84 (9th Cir. 2008). Absent such particularized facts, a plaintiff can only
 15 successfully invoke the core operations doctrine in the “*exceedingly rare circumstances*” where
 16 “the nature of the relevant fact is of such prominence that it would be absurd to suggest that
 17 management was without knowledge of the matter” (*Prodanova*, 993 F.3d at 1111-12) and that
 18 its omission rendered their statements “dramatically false.” *In re NVIDIA Corp. Sec. Litig.*, 768
 19 F.3d 1046, 1063 (9th Cir. 2014). That is not this case – for many reasons.

20 *First*, the only “fact” offered to support the allegation that the MBP program was a “core
 21 operation” is Kirk’s enthusiastic statements of support. ¶ 101; *see also* ¶¶ 95-100. This is
 22 obviously insufficient and ignores the fact that Precigen had many other business ventures which
 23 were far more advanced than the MBP program. *See, e.g.*, Ex. 1 at 6-16; Ex. 2 at 8-16; Ex. 3 at 7-
 24 14; *In re Twitter, Inc. Sec. Litig.*, 506 F. Supp. 3d 867, 889 (N.D. Cal. 2020) (core operations
 25 doctrine not applicable where affected business related to “only one component of [the
 26 Company’s] products”).

27 *Second*, Plaintiff’s bare allegation that the MBP program was of “central importance”
 28 does not permit an inference that *every* Defendant knew *every* detail about “every piece of

1 information . . . critical to the business’s core operations” (*Veal v. LendingClub Corp.*, 423 F.
2 Supp. 3d 785, 817 (N.D. Cal. 2019)) where, as here, the allegations do not show the MBP
3 program was “core” to Precigen and do not exclude the possibility the Individual Defendants
4 “may not even have been aware of” the omitted fact. *Twitter*, 506 F. Supp. 3d at 889. Kirk’s
5 statement that he “spen[t] a lot of time with . . . Walsh” (¶ 95) does not permit a “strong
6 inference” that Kirk (much less Messrs. Last, the COO who left in December 2017 and last
7 spoke in November 2017 (¶¶ 41, 42, 130, 137) or Sterling, the CFO who is mentioned in a single
8 paragraph and is not alleged to have said anything about the MBP program at all (¶ 20)) had
9 access to specific information about the lab testing, much less the source of methane being used
10 in the lab. *Oracle Partners, L.P. v. Concentric Analgesics, Inc.*, 2021 WL 2322351, at *5 (N.D.
11 Cal. June 7, 2021) (rejecting allegation that new drug trial was so “central” to Defendants’
12 success that all senior executives would know all details of interim results); *see also In re Nektar*
13 *Therapeutics*, 2020 WL 3962004, at *12-13 (N.D. Cal. July 13, 2020) (Defendants’ “scientific
14 backgrounds” and “involvement with the . . . program” does not suffice absent “specific
15 admissions . . . of detailed involvement in the minutia of a company’s [scientific] operations”).
16 Plaintiff’s conclusory assertion that Walsh kept the Individual Defendants apprised “does not
17 provide any particularized facts supporting an inference of scienter” because Plaintiff “offer[s]
18 no information on whether [Walsh] reported . . . about the details” of the methane used in
19 testing, when or with whom those conversations supposedly occurred, and there are no
20 “admissions by [any other Individual Defendant] that he closely monitored” those particular
21 details. *Prodanova*, 993 F.3d at 1109.

22 *Finally*, even if any Defendant was *aware* that laboratory testing was being conducted
23 using pure methane, “[k]nowledge of the [disputed information] is insufficient to infer that
24 [Defendants] acted with the intent to defraud or with deliberate recklessness in not reporting the
25 issue publicly.” *Twitter*, 506 F. Supp. 3d at 889 (emphasis added) (citation omitted). Here, there
26 are no allegations that Precigen could not or did not reach the same yields with natural gas as it
27 had for pure methane, or that the assumptions and inputs into the techno-economic model were
28 somehow inappropriate. Instead, “the Court is left to speculate” as to why the source of methane

1 used in the lab or the inputs into the financial model mattered “and thus whether [this] would
2 have been obvious to Defendants” when making the challenged statements. *In re Regulus*
3 *Therapeutics Inc. Sec. Litig.*, 406 F. Supp. 3d 845, 860 (S.D. Cal. 2019). Thus, “[e]ven
4 assuming, *arguendo*, that Plaintiff adequately pled that all of the defendants had knowledge of
5 the detail[s] of the lab testing or economic model], such an allegation does not support a strong
6 inference of scienter” because “the complaint does not allege that Defendants believed that [by]
7 not reporting information concerning [their scientific or forecasting methods] they were making
8 false or misleading statements.” *Rigel*, 697 F.3d at 883-84.

9 2. The Alleged Facts Actually Undermine Any Inference of Scienter

10 Because “a securities *fraud* lawsuit requires a showing of an intent to defraud investors[,]
11 [m]ere negligence — even head-scratching mistakes — does not amount to fraud. So [where, as
12 here,] the complaint fails to plead a plausible motive for the allegedly fraudulent action, the
13 plaintiff will face a substantial hurdle in establishing scienter.” *Prodanova*, 993 F.3d at 1103;
14 *Endologix*, 962 F.3d at 408, 415 (implausible that executives would knowingly overstate
15 likelihood of FDA approval without selling stock or reaping short-term profits).

16 Here, not only does the “lack of stock sale[] allegations detract from a scienter finding,”
17 the fact that Defendant Kirk and his controlled entities purchased more than \$180 million in new
18 shares during the Class Period and all of the Defendants increased their holdings “support[s] an
19 inference of innocence” not scienter. *Webb v. SolarCity Corp.*, 884 F.3d 844, 856 (9th Cir.
20 2018); Ex. 30; Ex. 31; Ex. 32; Ex. 33; Ex. 34 at 28; Ex. 35 at 15; Ex. 13 at 14. Indeed, in light of
21 the Individual Defendants’ significant investments in the Company and the Company’s
22 significant investments in the MBP program, Plaintiff’s theory of scienter simply “does not make
23 a whole lot of sense.” *Endologix*, 962 F.3d at 415-16. Just as in *Endologix*, Plaintiff’s
24 “allegations encounter an immediate first-level problem:” why would Defendants continue to
25 spend millions of dollars on the MBP program if they did not sincerely believe it was potentially
26 commercially viable? *Id.* Instead, here, as in *Endologix*, the far more plausible inference is that
27 Defendants genuinely believed in the MBP program’s potential. *Id.* at 415 (citing *Cozzarelli v.*
28 *Inspire Pharm. Inc.*, 549 F.3d 618, 627 (4th Cir. 2008) (rejecting “improbable” inference that a

1 company would continue scientific testing it “thought was doomed to failure”); *City of*
 2 *Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (rejecting “improbable”
 3 inference that company would spend millions testing new drug “if they did not believe their
 4 interpretation” of interim results or “thought the [outcome would be] a complete failure”).
 5 Defendants’ candid risk warnings and disclosures of actual challenges (*e.g.*, Ex. 5 at 8; Ex. 14 at
 6 7) are also inconsistent with any inference of scienter or fraud. *SolarCity*, 884 F.3d at 856.
 7 Finally, allegations regarding merger approvals and offerings (¶¶ 103-115) are insufficient to
 8 establish motive. *Bao v. SolarCity Corp.*, 2015 WL 1906105, at *4 (N.D. Cal. Apr. 27, 2015).

9 Considering all the allegations holistically, Plaintiff has not established that an inference
 10 of intentional or deliberately reckless conduct is as cogent and as compelling as an inference of
 11 nonculpable conduct, requiring dismissal. *Prodanova*, 993 F.3d at 1112-13.

12 **H. Plaintiff Fails to Plead Loss Causation**

13 As a threshold matter, Plaintiff’s failure to “plead with particularity and distinguish among
 14 the various misstatements and revelations that allegedly caused [the] decrease [in stock price],”
 15 “lump[ing] together [all the] alleged misstatements” with all the allegedly corrective disclosures
 16 over the three year class period (¶¶ 77-93), alone justifies dismissal. *See Irving Firemen’s Relief &*
 17 *Ret. Fund v. Uber Techs., Inc.*, 998 F.3d 397, 407-09 (9th Cir. 2021).

18 Even more fundamentally, Plaintiff’s loss causation theory fails because he does not
 19 plausibly allege that the purportedly “corrective” disclosures caused the market to “learn[] of and
 20 react[] to th[e] fraud, as opposed to merely reacting to reports of the defendant’s poor financial
 21 health generally.” *Loos v. Immersion Corp.*, 762 F.3d 880, 887-88 (9th Cir. 2014) (third alteration
 22 in original) (quoting *Metzler*, 540 F.3d at 1063). Here, the allegedly corrective disclosures in
 23 February and August 2019 (¶¶ 77-78, 81) and May and August 2020 (¶¶ 86, 88) did not reveal
 24 anything new or negative about the MBP program’s laboratory or financial modeling methods or
 25 its progress towards commercialization using natural gas. For example, the only news about the
 26 MBP program in the first allegedly corrective disclosure – Precigen’s February 2019 press release
 27 and analyst call – is overwhelmingly positive, *i.e.*, that “produc[tion of] 2,3 BDO from natural gas
 28 . . . has achieved 80% of the goal for the first small-scale plant operations” and that “[d]etailed

1 engineering design for [the Company’s] first-of-a-kind small-scale methane bioconversion facility
2 to 2,3 BDO is currently being bid out.” ¶ 158. Instead, the negative news in that announcement
3 was that “there is substantial doubt about [the Company’s] ability to continue as a going concern.”
4 ¶¶ 77-78 (alteration in SAC). The only negative news about the MBP program in the remaining
5 “corrective disclosures” was that despite its success in converting natural gas into 2,3 BDO,
6 Precigen lacked the cash to get the MBP program across the finish line. *See* Ex. 28 at 5, 6; Ex. 36
7 at 7; ¶¶ 81-82 (MBP program would be “sp[u]n off” to a new jointly-owned entity to “marshal
8 [Precigen’s] assets” and “focus” on health care); Ex. 22 at 5; Ex. 21 at 5; Ex. 4 at 26-27 (MBP
9 program suspended to preserve core health care business as Precigen’s overall financial condition
10 continued to deteriorate); Ex. 23 at 28 (now-suspended MBP operations’ assets were impaired).

11 These allegedly corrective disclosures about Precigen’s “disappointing [financial situation
12 did] not reveal *any* information from which . . . fraud [relating to the MBP program’s lab testing or
13 economic modeling methodologies] might reasonably be inferred.” *Loos*, 762 F.3d at 888
14 (emphasis added). While Plaintiff claims that these announcements were “corrective” because they
15 “effectively disclosed further new information as to just how little the Company’s MBP program
16 was worth” because “the state of its MBP development efforts was so poor” (¶ 86) as shown, there
17 are no particularized, creditable facts supporting such conclusions.

18 Finally, Plaintiff’s claims that the “truth” about Precigen’s alleged misstatements regarding
19 the MBP program were revealed to the market through (1) the March 2020 disclosure of the SEC
20 investigation (¶¶ 83-85) and (2) the September 2020 disclosure of the Order (¶¶ 91-92) also fail.
21 The Ninth Circuit has squarely held that “[t]he announcement of an [SEC] investigation . . . does
22 not qualify as a corrective disclosure” absent particular facts (*i.e.*, analyst and news reports)
23 demonstrating market speculation that the investigation suggested a prior statement was false, and
24 a “subsequent corrective disclosure *by the defendant*” confirming that speculation. *Lloyd v. CVB*
25 *Fin. Corp.*, 811 F.3d 1200, 1210 (9th Cir. 2016) (emphasis added) (citing *Loos*, 762 F.3d at 890);
26 *Rok v. Identiv, Inc.*, 2017 WL 35496, at *20 (N.D. Cal. Jan. 4, 2017) (dismissing claims on loss
27 causation grounds finding that “in *Lloyd*, it was far more clear . . . that the market had already
28 understood the fraud to have been revealed (based on the analysis of Dow Jones, Credit Suisse

1 and other analysts *at the time of the announcement of the SEC subpoena*), and that the corrective
2 disclosure [*by the defendant*] (that its largest borrower could not pay its loans) . . . actually
3 reveal[ed] the ‘truth’ about an earlier misrepresentation (that there was no serious doubt about the
4 largest borrower)” (emphasis added)), *aff’d sub nom. Cunningham v. Identiv, Inc.*, 716 F. App’x
5 663 (9th Cir. 2018). Here, there are no facts showing analysts speculated about the “meaning” of
6 the SEC investigation, *i.e.*, that it related to the source of methane used in the lab testing years
7 before, or that such speculation was confirmed by a later “admission” by Precigen. Thus, Plaintiff
8 cannot establish a viable loss causation theory. *Id.*; *cf. Lloyd*, 811 F.3d at 1210.

9 **I. Plaintiff Fails to State a Claim for Scheme Liability Under Rule 10b-5(a) or (c)**

10 To the extent Plaintiff purports to assert scheme liability under Rule 10b-5(a) or (c) (¶¶
11 178-180), such claims fail because they are not “premised on deceptive conduct that is
12 independent of misrepresentations or omissions.” *In re Mindbody, Inc. Sec. Litig.*, 489 F. Supp. 3d
13 188, 216, (S.D.N.Y. 2020); *see also In re Teva Sec. Litig.*, 512 F. Supp. 3d 321, 336-37 (D. Conn.
14 2021) (“Courts rightly insist that a plaintiff who intends to bring a Rule 10b-5 claim based on both
15 misstatement and scheme liability must do so clearly and specifically” and not merely “bypass the
16 elements ...[of] misstatement liability...by labeling the alleged misconduct a scheme.”).

17 **J. Plaintiff Fails to State A Section 20(a) Claim**

18 Because Plaintiff fails to plead a primary violation of the securities laws under Section
19 10(b), his claim under Section 20(a) must also be dismissed. *Align*, 856 F.3d at 623. The “control”
20 allegations are particularly deficient as to Walsh, only a Senior Vice President, as Plaintiff does
21 not plead any specific allegations that would suggest Walsh had power or control over any other
22 Defendant. *See, e.g., In re Int’l. Rectifier Corp. Sec. Litig.*, 2008 WL 4555794, at *22 (C.D. Cal.
23 May 23, 2008); *Middlesex Ret. System v. Quest Software, Inc.*, 527 F. Supp. 2d 1164, 1194 (C.D.
24 Cal. 2007).

25 **K. Plaintiff Should Not Be Granted Further Leave to Amend**

26 Given that Plaintiff has had two opportunities to amend its pleadings, the motion to dismiss
27 should be granted without further leave to amend.

28

1 DATED: November 3, 2021

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2
3 /s/ Nina F. Locker

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21 **ATTESTATION PURSUANT TO LOCAL RULE 5-1(h)(3)**

22 This certifies, pursuant to Local Rule 5-1(h)(3), that all signatories to this document
23 concur in its content and have authorized this filing.
24

25 DATED: November 3, 2021

26 /s/ Nina F. Locker

NINA F. LOCKER