

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

Individually and on
Behalf of All Others Similarly Situated,

Plaintiff,

v.

SKYE BIOSCIENCE, INC., PUNIT
DHILLON, KAITLYN ARSENAULT,
and CHRISTOPHER G. TWITTY,

Defendants.

Case No

CLASS ACTION

COMPLAINT FOR VIOLATIONS
OF THE FEDERAL SECURITIES
LAWS

DEMAND FOR JURY TRIAL

Plaintiff (“Plaintiff”), individually and on behalf of 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 information and belief as to all other matters,
based upon, *inter alia*, the investigation conducted by and through Plaintiff’s
attorneys, which included, among other things, a review of the Defendants’ public

1 documents, conference calls and announcements made by Defendants, United
2 States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and
3 press releases published by and regarding Skye Bioscience, Inc. (“Skye” or the
4 “Company”), analysts’ reports and advisories about the Company, and information
5 readily obtainable on the Internet. Plaintiff believes that substantial, additional
6 evidentiary support will exist for the allegations set forth herein after a reasonable
7 opportunity for discovery.
8
9

10 **NATURE OF THE ACTION**

11
12 1. This is a federal securities class action on behalf of a class consisting
13 of all persons and entities other than Defendants that purchased or otherwise
14 acquired Skye securities between November 4, 2024 and October 3, 2025, both
15 dates inclusive (the “Class Period”), seeking to recover damages caused by
16 Defendants’ violations of the federal securities laws and to pursue remedies under
17 Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange
18 Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of
19 its top officials.
20
21

22 2. Skye is a clinical stage biopharmaceutical company that focuses on
23 developing molecules that modulate G protein-coupled receptors (“GPCRs”) to
24
25
26
27
28

1 treat obesity, overweight,¹ and metabolic diseases. The Company’s lead product
2 candidate is nimacimab, a peripherally restricted negative allosteric modulating
3 antibody targeting cannabinoid receptor type-1 (“CB1”), a key GPCR involved in
4 metabolic regulation.
5

6 3. In August 2024, Skye initiated its “CBeyond” clinical trial, a twenty-
7 six-week, randomized, double-blind, placebo-controlled Phase 2a proof-of-concept
8 study designed to assess nimacimab as a treatment for obesity and overweight. The
9 CBeyond trial’s primary endpoint was to demonstrate an 8% difference in mean
10 weight loss using nimacimab versus placebo at twenty-six weeks, with a thirteen-
11 week follow-up.
12

13 4. At all relevant times while the Phase 2a Beyond trial was ongoing,
14 Defendants touted nimacimab’s purported “differentiated” mechanism of action
15 and efficacy results as purportedly demonstrated in other various studies. Critically,
16 Defendants cited to nimacimab’s purportedly potent efficacy as observed in these
17 various studies to suggest that the results of the Phase 2a CBeyond trial were likely
18 to be favorable, while consistently touting nimacimab’s overall clinical, regulatory,
19 and commercial prospects.
20
21
22
23

24
25
26 ¹ “Overweight” is a defined medical condition according to body mass index
27 (“BMI”). “Overweight” is defined, in adults, as having a BMI of 25 to 29.9,
28 whereas “obesity” is defined, in adults, as having a BMI of 30 or more. An
individual can “have” overweight or obesity.

1 5. Throughout the Class Period, Defendants made materially false and
2 misleading statements regarding Skye’s business, operations, and prospects.
3 Specifically, Defendants made false and/or misleading statements and/or failed to
4 disclose that: (i) nimacimab was less effective than Defendants had led investors to
5 believe; (ii) accordingly, nimacimab’s clinical, regulatory, and commercial
6 prospects were overstated; and (iii) as a result, Defendants’ public statements were
7 materially false and misleading at all relevant times.
8

9
10 6. On October 6, 2025, Skye issued a press release “announc[ing] the
11 topline data from its 26-week Phase 2a CBeyond™ proof-of-concept study of
12 nimacimab[.]” The press release disclosed that the “the nimacimab monotherapy
13 arm did not achieve the primary endpoint of weight loss compared to placebo” and
14 that “preliminary pharmacokinetic analysis showed lower than expected drug
15 exposure, potentially indicating the need for higher dosing as a monotherapy.”
16
17

18 7. On this news, Skye’s stock price fell \$2.85 per share, or **60%**, to close
19 at \$1.90 per share on October 6, 2025.
20

21 8. As a result of Defendants’ wrongful acts and omissions, and the
22 precipitous decline in the market value of the Company’s securities, Plaintiff and
23 other Class members have suffered significant losses and damages.
24
25
26
27
28

1 **JURISDICTION AND VENUE**

2 9. The claims asserted herein arise under and pursuant to Sections 10(b)
3 and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5
4 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).
5

6 10. This Court has jurisdiction over the subject matter of this action
7 pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.
8

9 11. Venue is proper in this District pursuant to Section 27 of the Exchange
10 Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Skye is headquartered in this
11 District, Defendants conduct business in this District, and a significant portion of
12 Defendants’ activities took place within this District.
13

14 12. In connection with the acts alleged in this complaint, Defendants,
15 directly or indirectly, used the means and instrumentalities of interstate commerce,
16 including, but not limited to, the mails, interstate telephone communications, and
17 the facilities of the national securities markets.
18

19 **PARTIES**

20 13. Plaintiff, as set forth in the attached Certification, acquired Skye
21 securities at artificially inflated prices during the Class Period and was damaged
22 upon the revelation of the alleged corrective disclosures.
23

24 14. Defendant Skye is a Nevada corporation with principal executive
25 offices located at 11250 El Camino Real, Suite 100, San Diego, California 92130.
26
27

1 The Company's common stock trades in an efficient market on the Nasdaq Global
2 Market ("NASDAQ") under the ticker symbol "SKYE."

3
4 15. Defendant Punit Dhillon ("Dhillon") has served as Skye's President
5 and Chief Executive Officer at all relevant times. During the Class Period,
6 Defendant Dhillon sold 82,910 shares of Skye stock for total proceeds of
7 approximately \$413,925.
8

9 16. Defendant Kaitlyn Arsenault ("Arsenault") has served as Skye's Chief
10 Financial Officer at all relevant times. During the Class Period, Defendant
11 Arsenault sold 86,612 shares of Skye stock for total proceeds of approximately
12 \$432,406.
13

14 17. Defendant Christopher G. Twitty ("Twitty") has served as Skye's
15 Chief Scientific Officer at all relevant times.
16

17 18. Defendants Dhillon, Arsenault, and Twitty are collectively referred to
18 herein as the "Individual Defendants."
19

20 19. The Individual Defendants possessed the power and authority to
21 control the contents of Skye's SEC filings, press releases, and other market
22 communications. The Individual Defendants were provided with copies of Skye's
23 SEC filings and press releases alleged herein to be misleading prior to or shortly
24 after their issuance and had the ability and opportunity to prevent their issuance or
25 to cause them to be corrected. Because of their positions with Skye, and their access
26
27
28

1 to material information available to them but not to the public, the Individual
2 Defendants knew that the adverse facts specified herein had not been disclosed to
3 and were being concealed from the public, and that the positive representations
4 being made were then materially false and misleading. The Individual Defendants
5 are liable for the false statements and omissions pleaded herein.
6

7
8 20. Skye and the Individual Defendants are collectively referred to herein
9 as “Defendants.”

10 **SUBSTANTIVE ALLEGATIONS**

11 **Background**

12
13 21. Skye is a clinical stage biopharmaceutical company that focuses on
14 developing molecules that modulate GPCRs to treat obesity, overweight, and
15 metabolic diseases. The Company’s lead product candidate is nimacimab, a
16 peripherally restricted negative allosteric modulating antibody targeting CB1, a key
17 GPCR involved in metabolic regulation.
18

19
20 22. On August 22, 2024, Skye initiated its “CBeyond” clinical trial, a
21 twenty-six-week, randomized, double-blind, placebo-controlled Phase 2a proof-of-
22 concept study designed to assess nimacimab as a treatment for obesity and
23 overweight. The CBeyond trial’s primary endpoint was to demonstrate an 8%
24 difference in mean weight loss using nimacimab versus placebo at twenty-six
25 weeks, with a thirteen-week follow-up. The trial’s secondary and exploratory
26
27
28

1 endpoints evaluated safety, tolerability, neuropsychiatric and cognitive outcomes,
2 and change in body composition, as well as assessed synergistic outcomes of
3 nimacimab in combination with semaglutide, a GLP-1 receptor agonist.
4

5 23. At all relevant times while the Phase 2a Beyond trial was ongoing,
6 Defendants touted nimacimab’s purported “differentiated” mechanism of action
7 and efficacy results as purportedly demonstrated in other various studies. Critically,
8 Defendants cited to nimacimab’s purportedly potent efficacy as observed in these
9 various studies to suggest that the results of the Phase 2a CBeyond trial were likely
10 to be favorable, while consistently touting nimacimab’s overall clinical, regulatory,
11 and commercial prospects.
12
13

14 **Materially False and Misleading Statements Issued During the Class Period**
15

16 24. The Class Period begins on November 4, 2024, when Skye issued a
17 press release during pre-market hours announcing preliminary data from a diet-
18 induced obesity (“DIO”) model in mice. The press release stated, *inter alia*, that
19 “[p]eripherally-restricted nimacimab achieve[d] significant dose-dependent weight
20 loss, fat mass reduction, lean mass preservation, and glycemic control in [DIO]
21 model[,]” and that “[p]reliminary data shows that nimacimab achieves desired
22 metabolic outcomes[.]”
23
24
25
26
27
28

1 25. On November 7, 2024, Skye issued a press release reporting its
2 financial results for the third quarter (“Q3”) of 2024 and recent business highlights.

3
4 The press release quoted Defendant Dhillon as stating, in relevant part²:

5 The third quarter marked an important transition for Skye as a
6 metabolic-focused company with the launch of our Phase 2 obesity
7 clinical trial for nimacimab. *We believe our truly peripherally-*
8 *restricted CB1 inhibitor has the differentiated attributes necessary to*
9 *realize the unique benefits of this class of drug within the overall*
10 *obesity landscape* We also recently announced new preclinical
11 data from a [DIO] model in mice. *Nimacimab achieved significant*
12 *dose-dependent weight loss of up to 16% compared to vehicle,*
13 *highlighting the prominent role of peripherally-driven CB1 inhibition*
14 *to induce weight loss and other metabolic benefits* without relying on
15 central CB1 inhibition and its risk of neuropsychiatric adverse events.

16 26. The same day, Skye hosted a conference call with investors and
17 analysts to discuss its Q3 2024 financial results and business updates. During his
18 prepared remarks on the call, Defendant Dhillon stated, in relevant part, that “we
19 believe nimacimab’s first-in-class profile as a perfectly targeting CB1 inhibitor
20 offers the right combination of efficacy and safety that position it to realize a
21 significant opportunity for CB1 inhibition to drive meaningful dose and weight loss,
22 fat mass reduction and lean mass preservation, improve glycemic control and
23 weight loss, and achieve other metabolic benefits[.]”

24 27. On the same call, in response to an analyst’s question regarding
25 preclinical data that Skye had presented during a recent professional event,
26

27
28 ² All emphases hereinafter are added unless otherwise indicated.

1 Defendant Dhillon stated, *inter alia*, that “the key takeaway is that, there’s really
2 strong preclinical efficacy of nimacimab” and “[i]t’s demonstrating a significant
3 dose dependent weight loss and it’s shown this improvement in terms of glucose
4 metabolism, as well as lean mass preservation[,] which purportedly “point[s]
5 towards a favorable impact on body composition as well.”
6

7
8 28. Also on November 7, 2024, Skye filed a quarterly report on Form 10-
9 Q with the SEC, reporting the Company’s financial and operating results for its Q3
10 ended September 30, 2024 (the “Q3 2024 10-Q”). The Q3 2024 10-Q stated, in
11 relevant part:
12

13 During November 2024, we shared initial data from our DIO study *with*
14 *nimacimab showing dose-dependent weight loss as well as positive*
15 *changes in body composition and glycemic control upon treatment.*
16 Further analysis and repeat studies are underway but we believe that
17 true peripheral CB1 inhibition can positively impact metabolic
disorders including obesity.

18 *Given the distinct mechanism and beneficial attributes of nimacimab*
19 *as a peripheral CB1 inhibitor, within the large and heterogeneous*
20 *obesity landscape we believe there is significant opportunity for*
21 *nimacimab to potentially complement GLP-1 agonists and other anti-*
22 *obesity drug mechanisms of action as well as to have a potential role*
23 *as a monotherapy.*

24 29. Appended as exhibits to the Q3 2024 10-Q were signed certifications
25 pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”), wherein Defendants Dhillon
26 and Arsenault certified, in relevant part, that the Q3 2024 10-Q “does not contain
27 any untrue statement of a material fact or omit to state a material fact necessary to
28

1 make the statements made, in light of the circumstances under which such
2 statements were made, not misleading with respect to the period covered by this
3 report[.]”

4
5 30. On March 20, 2025, Skye issued a press release reporting its financial
6 results for the fourth quarter (“Q4”) and full year (“FY”) of 2024, as well as certain
7 business updates. The press release stated, *inter alia*, that the “[i]nitial data from
8 our [DIO] model in mice released in November 2024 . . . supports our hypothesis
9 that nimacimab’s peripherally-targeted CB1 inhibition drives significant weight
10 loss and improved metabolic parameters, consistent with the compound’s
11 differentiated mechanism of action.”

12
13
14 31. The same press release also quoted Defendant Dhillon as stating, in
15 relevant part:

16
17 Skye’s prime accomplishment in 2024 was the initiation and rapid
18 advancement of its comprehensive Phase 2a clinical study of
19 nimacimab ***We believe nimacimab’s product profile is well-***
20 ***positioned to potentially fulfill critical unmet needs in this rapidly***
evolving therapeutic area.

21 * * *

22
23 We surpassed our enrollment target ahead of schedule and have to-date
24 executed the Phase 2a clinical plan on target and within our budget. ***We***
disclosed preclinical data in November 2024 which achieved
25 ***significant dose-dependent weight loss, significant fat mass loss with***
lean mass preservation, and dose-dependent improvement in glucose
26 ***tolerance. These outcomes are indicative of the potentially compelling***
attributes of Skye’s highly peripherally-restricted CB1 inhibitor.

1 32. Also on March 20, 2025, Skye hosted a conference call with investors
2 and analysts to discuss its Q4 and FY 2024 financial results and business updates.
3 During his prepared remarks on the call, Defendant Dhillon touted Skye’s purported
4 “demonstration that nimacimab can drive significant weight loss in a [DIO]
5 mirroring model[,]” that Defendants “look forward to sharing even more data that
6 demonstrates the ability of nimacimab to not only drive weight loss, but also impact
7 multiple metabolic processes associated with obesity and its comorbidity[,]” and
8 that, “to date, nimacimab’s truly peripheral mechanism has demonstrated
9 meaningful weight loss[.]”
10
11

12
13 33. The same day, Skye filed an annual report on Form 10-K with the SEC,
14 reporting the Company’s financial and operating results for its Q4 and FY ended
15 December 31, 2024 (the “2024 10-K”). The 2024 10-K stated, *inter alia*:
16

17 ***We believe nimacimab stands apart from GLP-1’s and other incretin-***
18 ***based weight loss therapies because its primary mechanism goes***
19 ***beyond suppression of food intake. While peripheral CB1 inhibition***
20 ***can reduce elevated leptin levels as well as modulate appetite-***
21 ***regulating hormones to broadly blunt appetite, key additional drivers of***
22 ***weight loss include increased energy expenditure, fat metabolism, and***
23 ***insulin sensitivity as well as reduced inflammation. As a result, clinical***
24 ***data from this class of drugs have demonstrated not only weight loss***
25 ***but also lean mass preservation, improved insulin sensitivity, and***
26 ***reductions in cholesterol. Additionally, preclinical obesity models***
27 ***using CB1 inhibitors have shown improvements in hyperleptinemia,***
28 ***leptin sensitivity, and increased energy expenditure. This unique***
mechanism offers a potential alternative, and even complementary,
approach to chronic weight management, broadening therapeutic
options for patients with obesity and overweight.

1 * * *

2 Nimacimab functions as a negative allosteric modulator of CB1, which
3 means it binds to a distinct area of CB1 ‘away’ from the receptor’s
4 primary active site (the orthosteric site) ***and thus inhibits CB1 activity***
5 ***without any competition from the endogenous ligands***
6 ***(endocannabinoids). This noncompetitive mode of action is distinct***
7 ***from small-molecule inhibitors***, which target CB1 receptor’s
8 orthosteric site and require successful competition with
9 endocannabinoids for receptor occupancy to inhibit CB1 signaling.
10 This can become critical as CB1 signaling is often overactive in
11 metabolic diseases, and direct competition with an inverse agonist may
12 be insufficient in tissues with excessive CB1 activity. In such disease
13 states, where both CB1 receptor density and endocannabinoid levels are
14 elevated, orthosteric small molecules must outcompete high
15 concentrations of endocannabinoids, which can negatively impact their
16 Pharmacokinetic (“PK”) profile and ultimately limit their efficacy.

17 34. Appended as exhibits to the 2024 10-K were substantively the same
18 SOX certifications as referenced in ¶ 29, *supra*, signed by Defendants Dhillon and
19 Arsenault.

20 35. On April 15, 2025, Skye issued a press release announcing new
21 preclinical data for nimacimab in a murine DIO model. The press release stated,
22 *inter alia*, that “after 25 days of treatment, results demonstrated . . . [g]reater than
23 30% weight loss when nimacimab was combined with the dual GLP-1/GIP agonist,
24 tirzepatide” and “[n]imacimab alone demonstrated 23.5% weight loss, comparable
25 to monlunabant and tirzepatide alone.”

26 36. The same press release quoted Defendant Dhillon as stating:

27 ***This new preclinical study highlights that a truly peripherally-***
28 ***restricted CB1 inhibitor—nimacimab—effectively drives weight loss***

1 in a DIO model. *Nimacimab compared favorably to and provided*
2 *significant additive weight loss when combined with GLP-1-targeted*
3 *drugs like tirzepatide* Using higher doses, this study builds on our
4 previous preclinical DIO data in human CB1 knock-in mice *that*
5 *showed significant dose-dependent weight loss.* Biomarker analyses
6 demonstrated that *nimacimab-driven weight loss was associated with*
7 *beneficial changes in key hormones, glycemic control, and*
8 *inflammatory markers.*

9 []Skye believes *nimacimab shows potential both as a monotherapy*
10 *and in combination with a GLP-1 targeted drug to address unmet*
11 *needs in obesity with the potential to change weight loss standards of*
12 *care.* Initial data from Skye’s Phase 2a study in obesity is expected in
13 late Q3/early Q4 2025.[]

14 [. . . .] The second key finding of this animal study is that Skye’s highly-
15 peripherally restricted *nimacimab drives efficacy similar to a less-*
16 *peripherally restricted CB1 inhibitor, monlunabant,* in a DIO model.
17 *These in vivo data continue to support our belief that our*
18 *differentiated antibody approach can potentially provide meaningful*
19 *efficacy[.]*

20 37. On May 8, 2025, Skye issued a press release reporting its financial
21 results for the first quarter (“Q1”) of 2025 “and Highlight[ing] Nimacimab
22 Differentiation in Obesity[.]” The press release stated, *inter alia*, that “[n]imacimab
23 in combination with tirzepatide improves weight loss effect over tirzepatide alone,
24 and shows comparable weight loss to monlunabant and tirzepatide alone in
25 preclinical [DIO] model[.]”

26 38. The same press release also stated that “[i]n vitro data reported from
27 new preclinical study highlights superior potency of . . . nimacimab[] versus
28 monlunabant when tested under pathological levels of CB1 agonists[.]”

1 *complement significant glycemic control as well as productive*
2 *modulation of key appetite-regulating hormones including GLP-1*
3 *and leptin.*

4 *Additional data sets also highlighted significant reduction of*
5 *inflammation in adipose tissue as well as liver steatosis.* We are also
6 happy to report that this initial study has now been repeated by an
7 independent lab *with very reproducible results not only in terms of the*
8 *magnitude of weight loss and body composition that is preservation*
9 *of lean mass with significant reduction of fat mass, but also with*
10 *positive changes in glycemic control.*

11 This repeat study also looked carefully at food consumption and noted
12 a *significant reduction in cumulative caloric intake slightly less but*
13 *in line with Semaglutide. Collectively, these studies highlight that*
14 *Nimacimab-dependent efficacy is driven by multiple peripheral*
15 *pathways coordinated through different organ systems.*

16 42. Defendant Twitty likewise asserted during his prepared remarks, *inter*
17 *alia*, that study “results combined with our mechanistic data strongly support the
18 potential for Nimacimab to be effective as both a Monotherapy and as part of a
19 combination approach to address the growing obesity epidemic[,]” that “*in vivo*
20 studies continue to support our belief that our differentiated antibody approach can
21 provide meaningful efficacy[,]” and that “[t]hese data suggest that Nimacimab may
22 offer the widest possible therapeutic window among CB1 inhibitors potentially
23 delivering significant metabolic benefits[.]”

24 43. On the same call, in response to an analyst’s question regarding how
25 the results from Skye’s preclinical studies, including the mouse DIO study,
26 informed Defendants’ confidence in the anticipated topline results from the Phase
27

1 2a CBeyond trial, Defendant Dhillon stated, *inter alia*, that “across the board it
2 checks a lot of boxes” and “[o]f course it gives you this aspect of well we feel more
3 confident around the mechanism and there’s this component that comes along with
4 it that we expect it to translate into the clinic.”

6 44. Likewise, in response to the same question, Defendant Twitty stated,
7
8 *inter alia*:

9 So when you look at that all together, you really start to appreciate how
10 we’re matching exposure and ***we’re looking at doses that are we feel
11 very translatable.*** And we’ve seen some success with predicting
12 efficacy in the interim space and arguably looking at the CB1 space
13 with Novo’s data set which we feel is actually a pretty significant data
14 set. This is actually a very I think a very strong data set and they too
15 had DIO data that looked pretty strong. ***We reproduced that in our own
16 lab. So coming back to this idea of translating we do feel pretty
17 confident that we’re going to have an active drug in the clinic.***

18 45. Also on May 9, 2025, Skye filed a quarterly report on Form 10-Q with
19 the SEC, reporting the Company’s financial and operating results for its Q1 ended
20 March 31, 2025 (the “Q1 2025 10-Q”). The Q1 2025 10-Q stated, in relevant part:

21 During the three months ended March 31, 2025, we announced
22 preclinical data ***supporting our hypothesis that . . . nimacimab[] is able
23 to drive similar efficacy when compared to a less-peripherally
24 restricted CB1 inhibitor, monlunabant, in a [DIO] murine model.*** The
25 results of the preclinical DIO study ***demonstrated greater than 30%
26 weight loss when nimacimab was combined with the dual GLP-1/GIP
27 agonist, tirzepatide. Nimacimab alone demonstrated 23.5% weight
28 loss, which is comparable to monlunabant and tirzepatide alone in
this study.***

We also shared *in vitro* potency data ***demonstrating that nimacimab’s
non-competitive allosteric binding to CB1 provides potential***

1 ***advantages over orthosteric-binding small-molecule drugs.*** Binding
2 to a different site on the receptor, nimacimab does not compete with
3 natural CB1 agonists such as anandamide (AEA) and 2-
4 arachidonoylglycerol (2-AG). It can block CB1 activity even with an
5 elevated concentration of CB1 agonists, which is associated with
6 obesity. In contrast, orthosteric-binding small molecule inhibitors must
7 compete with CB1 agonists for binding at the receptor’s orthosteric site,
8 which was shown to negatively impact potency when tested under
9 elevated CB1 agonist concentrations. ***This distinction may give
10 nimacimab a wider therapeutic window, with suitable potency at
11 lower doses and less side effects.***

12 ***Given the distinct mechanism and beneficial attributes of nimacimab
13 as a peripheral CB1 inhibitor, within the large and heterogeneous
14 obesity landscape we believe there is significant opportunity for
15 nimacimab to potentially complement GLP-1 agonists and other anti-
16 obesity drug mechanisms of action as well as have a potential role
17 as a monotherapy.***

18 46. Appended as exhibits to the Q1 2025 10-Q were substantively the same
19 SOX certifications as referenced in ¶ 29, *supra*, signed by Defendants Dhillon and
20 Arsenault.

21 47. On June 23, 2025, Skye issued a press release announcing the debut of
22 its “*Anatomy of Progress*” nimacimab development update video series and the
23 availability of presentations related to the development of nimacimab. The press
24 release quoted Defendant Dhillon as stating, in relevant part:

25 Unlike the small molecule CB1 inhibitors currently in development,
26 ***nimacimab’s differentiating peripheral restriction has the potential to
27 demonstrate the same weight loss and metabolic benefits previously
28 seen in clinical trials by first-generation CB1 inhibitors,*** without the
significant neuropsychiatric liabilities that continue to plague its small
molecule counterparts. ***So nimacimab is not just another anti-obesity***

1 *drug, it represents a new frontier in how we think about fat*
2 *metabolism, safety and long-term care.*

3 48. On August 7, 2025, Skye issued a press release reporting its financial
4 results for the second quarter (“Q2”) of 2025 and business updates. The press
5 release stated, *inter alia*, that a “[n]ew preclinical study highlights [the] superior
6 weight rebound profile of nimacimab compared to incretin therapy[,]” that
7 “[p]reclinical data shows dosing nimacimab in combination with a low dose of
8 tirzepatide resulted in enhanced weight loss compared to an optimal dose of
9 tirzepatide[,]” and that, “[u]sed as a maintenance treatment, a preclinical study of
10 nimacimab reduced the weight rebound effect observed in mice treated with
11 tirzepatide alone or in combination with nimacimab.”

12 49. The same press release also quoted Defendant Dhillon as stating, in
13 relevant part:
14

15 We believe nimacimab’s peripherally-restricted CB1 mechanism
16 represents a fundamentally different approach, *one that could offer*
17 *real-world advantages as a monotherapy or in combination*, without
18 compounding gastrointestinal side effects. As the market evolves, we
19 see a growing need for therapies that deliver broader metabolic benefit,
20 improved persistence, and combinability and *we believe nimacimab is*
21 *uniquely positioned to help define this next chapter in obesity care.*
22

23 50. Also on August 7, 2025, Skye hosted a conference call with investors
24 and analysts to discuss its Q2 2025 financial results and business updates. During
25 his prepared remarks on the call, Defendant Dhillon discussed at length
26 nimacimab’s observed efficacy, as well as its potential clinical, regulatory, and
27

1 commercial prospects. For example, Defendant Dhillon touted, *inter alia*,
2 nimacimab’s purported “robust, reproducible and mechanistically distinct” results
3 in the Company’s DIO models, as well as the drug’s “demonstrat[ion of] durable
4 posttreatment weight loss compared to incretin therapy after the therapy stopped[,]”
5 representing that “[n]imacimab is not just an alternative” but “a next-generation
6 backbone candidate for durable, combinable and more accessible obesity care” with
7 “a platform that can potentially extend beyond monotherapy to life cycle expansion
8 across lines of therapy and patient segments that are currently underserved by
9 today’s options.”

13 51. The same day, Skye filed a quarterly report on Form 10-Q with the
14 SEC, reporting the Company’s financial and operating results for its Q2 ended June
15 30, 2025 (the “Q2 2025 10-Q”). The Q2 2025 10-Q stated, *inter alia*:

17 We recently shared new data from a preclinical [DIO] mouse model
18 *which provides further evidence for the potential combination of*
19 *nimacimab with incretins and demonstrated the potential durability*
20 *of response with nimacimab as a monotherapy or maintenance*
21 *therapy post-incretin treatment* The preclinical DIO study also
22 demonstrated that, *when used as a monotherapy, nimacimab-driven*
23 *weight loss persisted for about 20 days after treatment cessation,*
24 *while mice treated with tirzepatide alone regained most of their lost*
25 *weight within a week post-treatment.* Lastly, the preclinical DIO study
26 demonstrated that *when nimacimab alone was used after an initial*
27 *tirzepatide or combination treatment in the preclinical DIO mouse*
28 *model, it reduced rebound weight gain in these groups of mice.*

1 52. Appended as exhibits to the Q2 2025 10-Q were substantively the same
2 SOX certifications as referenced in ¶ 29, *supra*, signed by Defendants Dhillon and
3 Arsenault.
4

5 53. The statements referenced in ¶¶ 24-52 were materially false and
6 misleading because Defendants made false and/or misleading statements, as well as
7 failed to disclose material adverse facts about Skye’s business, operations, and
8 prospects. Specifically, Defendants made false and/or misleading statements and/or
9 failed to disclose that: (i) nimacimab was less effective than Defendants had led
10 investors to believe; (ii) accordingly, nimacimab’s clinical, regulatory, and
11 commercial prospects were overstated; and (iii) as a result, Defendants’ public
12 statements were materially false and misleading at all relevant times.
13
14
15

16 54. Defendants likewise violated Item 303 of SEC Regulation S-K, 17
17 C.F.R. § 229.303(b)(2)(ii) (“Item 303”), which required Skye to “[d]escribe any
18 known trends or uncertainties that have had or that are reasonably likely to have a
19 material favorable or unfavorable impact on net sales or revenues or income from
20 continuing operations.” Defendants’ failure to disclose that nimacimab was less
21 effective than they had led investors to believe, and that nimacimab’s clinical,
22 regulatory, and commercial prospects were overstated, violated Item 303 because
23 these issues represented known trends or uncertainties that were likely to have a
24 material unfavorable impact on the Company’s business and financial results.
25
26
27
28

1 **The Truth Emerges**

2 55. On October 6, 2025, during pre-market hours, Skye issued a press
3 release announcing topline data from its Phase 2a CBeyond clinical trial, revealing
4 that the trial had failed to meet its primary endpoint. Specifically, the press release
5 stated, *inter alia*:
6

- 7
- 8 • *Nimacimab monotherapy did not meet its primary endpoint for*
9 *weight loss; preliminary pharmacokinetic analysis showed lower*
10 *than expected drug exposure, potentially indicating the need for*
11 *higher dosing as a monotherapy.*

12 * * *

13 In CBeyond™, the nimacimab monotherapy arm did not achieve the
14 primary endpoint of weight loss compared to placebo (-1.52% vs. -0.26
15 for placebo, mITT1). Preliminary pharmacokinetic analysis showed an
16 association between exposure and response, suggesting that the 200
17 mg, subcutaneous weekly dose was suboptimal as a monotherapy.

18 * * *

19 **CBeyond™ Phase 2a Topline Results at 26 Weeks**

- 20 • **Monotherapy dosed at 200 mg demonstrated lower than**
21 **expected drug exposure.** In the monotherapy arm, nimacimab 200
22 mg did not achieve the primary endpoint, with placebo-subtracted
23 weight loss of -1.26% at week 26 (p=0.2699, mITT). Preliminary
24 pharmacokinetic analysis showed lower than expected drug
25 exposure of nimacimab, supporting evaluation of higher dosing.

26 (Emphases in original.)

27 56. On this news, Skye’s stock price fell \$2.85 per share, or **60%**, to close
28 at \$1.90 per share on October 6, 2025.

1 were made, not misleading; and employed devices, schemes and artifices to defraud
2 in connection with the purchase and sale of securities. Such scheme was intended
3 to, and, throughout the Class Period, did: (i) deceive the investing public, including
4 Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and
5 maintain the market price of Skye securities; and (iii) cause Plaintiff and other
6 members of the Class to purchase or otherwise acquire Skye securities and options
7 at artificially inflated prices. In furtherance of this unlawful scheme, plan and
8 course of conduct, Defendants, and each of them, took the actions set forth herein.
9
10

11
12 72. Pursuant to the above plan, scheme, conspiracy and course of conduct,
13 each of the Defendants participated directly or indirectly in the preparation and/or
14 issuance of the quarterly and annual reports, SEC filings, press releases and other
15 statements and documents described above, including statements made to securities
16 analysts and the media that were designed to influence the market for Skye
17 securities. Such reports, filings, releases and statements were materially false and
18 misleading in that they failed to disclose material adverse information and
19 misrepresented the truth about Skye's finances and business prospects.
20
21

22
23 73. By virtue of their positions at Skye, Defendants had actual knowledge
24 of the materially false and misleading statements and material omissions alleged
25 herein and intended thereby to deceive Plaintiff and the other members of the Class,
26 or, in the alternative, Defendants acted with reckless disregard for the truth in that
27
28

1 they failed or refused to ascertain and disclose such facts as would reveal the
2 materially false and misleading nature of the statements made, although such facts
3 were readily available to Defendants. Said acts and omissions of Defendants were
4 committed willfully or with reckless disregard for the truth. In addition, each
5 Defendant knew or recklessly disregarded that material facts were being
6 misrepresented or omitted as described above.
7
8

9 74. Information showing that Defendants acted knowingly or with reckless
10 disregard for the truth is peculiarly within Defendants' knowledge and control. As
11 the senior managers and/or directors of Skye, the Individual Defendants had
12 knowledge of the details of Skye's internal affairs.
13

14 75. The Individual Defendants are liable both directly and indirectly for
15 the wrongs complained of herein. Because of their positions of control and
16 authority, the Individual Defendants were able to and did, directly or indirectly,
17 control the content of the statements of Skye. As officers and/or directors of a
18 publicly-held company, the Individual Defendants had a duty to disseminate timely,
19 accurate, and truthful information with respect to Skye's businesses, operations,
20 future financial condition and future prospects. As a result of the dissemination of
21 the aforementioned false and misleading reports, releases and public statements, the
22 market price of Skye securities was artificially inflated throughout the Class Period.
23
24
25
26
27
28

1 which were concealed by Defendants, Plaintiff and the other members of the Class
2 purchased or otherwise acquired Skye securities at artificially inflated prices and
3 relied upon the price of the securities, the integrity of the market for the securities
4 and/or upon statements disseminated by Defendants, and were damaged thereby.
5

6 76. During the Class Period, Skye securities were traded on an active and
7 efficient market. Plaintiff and the other members of the Class, relying on the
8 materially false and misleading statements described herein, which the Defendants
9 made, issued or caused to be disseminated, or relying upon the integrity of the
10 market, purchased or otherwise acquired shares of Skye securities at prices
11 artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other
12 members of the Class known the truth, they would not have purchased or otherwise
13 acquired said securities, or would not have purchased or otherwise acquired them
14 at the inflated prices that were paid. At the time of the purchases and/or acquisitions
15 by Plaintiff and the Class, the true value of Skye securities was substantially lower
16 than the prices paid by Plaintiff and the other members of the Class. The market
17 price of Skye securities declined sharply upon public disclosure of the facts alleged
18 herein to the injury of Plaintiff and Class members.
19
20
21
22

23 77. By reason of the conduct alleged herein, Defendants knowingly or
24 recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act
25 and Rule 10b-5 promulgated thereunder.
26
27
28

1 82. Because of their positions of control and authority as senior officers,
2 the Individual Defendants were able to, and did, control the contents of the various
3 reports, press releases and public filings which Skye disseminated in the
4 marketplace during the Class Period concerning Skye’s results of operations.
5 Throughout the Class Period, the Individual Defendants exercised their power and
6 authority to cause Skye to engage in the wrongful acts complained of herein. The
7 Individual Defendants, therefore, were “controlling persons” of Skye within the
8 meaning of Section 20(a) of the Exchange Act. In this capacity, they participated
9 in the unlawful conduct alleged which artificially inflated the market price of Skye
10 securities.
11
12
13

14 83. Each of the Individual Defendants, therefore, acted as a controlling
15 person of Skye. By reason of their senior management positions and/or being
16 directors of Skye, each of the Individual Defendants had the power to direct the
17 actions of, and exercised the same to cause, Skye to engage in the unlawful acts and
18 conduct complained of herein. Each of the Individual Defendants exercised control
19 over the general operations of Skye and possessed the power to control the specific
20 activities which comprise the primary violations about which Plaintiff and the other
21 members of the Class complain.
22
23
24

25 84. By reason of the above conduct, the Individual Defendants are liable
26 pursuant to Section 20(a) of the Exchange Act for the violations committed by Skye.
27
28

