UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Plaintiff, v. ACELYRIN, INC., SHAO-LEE LIN, MARDI C. DIER, and GIL LABRUCHERIE, Defendants.	Case No. CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

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 documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding ACELYRIN, Inc. ("Acelyrin" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Acelyrin securities between May 4, 2023 and September 11, 2023, both dates inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Acelyrin is a clinical biopharma company that focuses on developing and commercializing transformative medicines. The Company's lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with purportedly high potency, which is currently in Part B of a Phase 2b/3 clinical trial for use in the treatment of moderate to severe Hidradenitis Suppurativa ("HS").

3. On April 13, 2023, Acelyrin filed a registration statement on Form S-1 with the SEC in connection with the Company's Initial Public Offering ("IPO"), which, after several amendments, was declared effective by the SEC on May 4, 2023 (the "Registration Statement").

4. On May 4, 2023, pursuant to the Registration Statement, Acelyrin's common stock began publicly trading on the Nasdaq Global Select Market ("NASDAQ") under the trading symbol "SLRN".

5. On May 5, 2023, Acelyrin filed a prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement (the "Prospectus" and, collectively with the Registration Statement, the "Offering Documents").

6. Pursuant to the Offering Documents, Acelyrin issued 30 million shares of its common stock to the public at the Offering price of $18.00 per share for proceeds to the Company of $502.2 million after applicable underwriting discounts and commissions.

7. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) izokibep was less effective in treating HS than Defendants had led investors to believe; (ii) accordingly, Acelyrin overstated izokibep's clinical and/or commercial prospects; (iii) as a result, Acelyrin also overstated the Company's business prospects

post-IPO; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

8. On September 11, 2023, after the markets closed, Acelyrin announced disappointing top-line results from Part B of the Phase 2b/3 trial evaluating izokibep for the treatment of moderate-to-severe HS. Specifically, izokibep failed to show statistically significant reduction in abscesses and inflammatory nodules in patients as compared to placebo.

9. On this news, Acelyrin's stock price fell $17.19 per share, or 61.61%, over the following two trading sessions, to close at $10.71 per share on September 13, 2023.

10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Acelyrin's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

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

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

13. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Acelyrin is headquartered in

this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

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

PARTIES

15. Plaintiff, as set forth in the attached Certification, acquired Acelyrin securities at artificially inflated prices during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

16. Defendant Acelyrin is a Delaware corporation with principal executive offices located at 4149 Liberty Canyon Road, Agoura Hills, California 91301. The Company's common stock trades in an efficient market on the NASDAQ under the trading symbol "SLRN".

17. Defendant Shao-Lee Lin ("Lin") has served as Acelyrin's Founder, Chief Executive Officer, and a Director of the Company at all relevant times.

18. Defendant Mardi C. Dier ("Dier") served as Acelyrin's Chief Financial Officer ("CFO") and Chief Business Officer from before the start of the Class Period to August 15, 2023.

19. Defendant Gil Labrucherie ("Labrucherie") has served as Acelyrin's CFO since August 15, 2023.

20. Defendants Lin, Dier, and Labrucherie are sometimes referred to herein collectively as the "Individual Defendants".

21. The Individual Defendants possessed the power and authority to control the contents of Acelyrin's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Acelyrin's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Acelyrin, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

22. Acelyrin and the Individual Defendants are sometimes referred to herein collectively as the "Defendants".

SUBSTANTIVE ALLEGATIONS

Background

23. Acelyrin is a clinical biopharma company that focuses on identifying, acquiring, and accelerating the development and commercialization of transformative

medicines. The Company's lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with purportedly high potency, which is presently in Part B of Phase 2b/3 clinical trials for use in the treatment of moderate to severe HS.

24. On April 13, 2023, Acelyrin filed the Registration Statement on Form S-1 with the SEC in connection with the IPO, which, after several amendments, was declared effective by the SEC on May 4, 2023.

25. On May 4, 2023, pursuant to the Registration Statement, Acelyrin's common stock began publicly trading on the NASDAQ under the trading symbol "SLRN".

26. On May 5, 2023, Acelyrin filed the Prospectus on Form 424B4 with the SEC in connection with the IPO, which incorporated and formed part of the Registration Statement.

27. Pursuant to the Offering Documents, Acelyrin issued 30 million shares of its common stock to the public at the Offering price of $18.00 per share for proceeds to the Company of $502.2 million after applicable underwriting discounts and commissions.

Materially False and Misleading Statements Issued During the Class Period

28. The Class Period begins on May 4, 2023, when Acelyrin's common stock began publicly trading on the NASDAQ pursuant to the materially false or misleading statements or omissions in the Offering Documents. For example, in providing an overview of the Company, the Offering Documents stated, in relevant part:

> ACELYRIN is a late-stage clinical biopharma company focused on identifying, acquiring, and accelerating the development and

commercialization of transformative medicines. We are driven by our sense of urgency to bring life-changing therapies to patients globally, a core value that we refer to as "courageous caring."

Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe may provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-interleukin (IL)-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are "diamonds in the rough," where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those benefits could mean for patients. Subsequently, we plan to utilize the results from initial clinical trials and the learnings we obtain from emerging biology to potentially expand the application of our candidates to other indications in which there are significant unmet needs.

Our current portfolio consists of multiple clinical and preclinical stage product candidates being investigated across several indications representing multi-billion-dollar opportunities in the aggregate.

Our Pipeline

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity and the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody.

29. Further, the Offering Documents touted that "[t]he [d]esign of Izokibep is [h]ighly [d]ifferentiated from [m]onoclonal [a]ntibodies," and stated, in relevant part:

Izokibep is a small protein therapeutic designed to bind the homodimeric IL-17A molecule with high potency. In contrast to conventional monoclonal antibodies, izokibep is much smaller – approximately one-tenth

the size of a traditional monoclonal antibody – containing two IL-17A binding domains and an albumin binding domain that results in improved pharmacokinetic (PK) properties.

By virtue of its structure and size, we believe izokibep has several key features different from traditional monoclonal antibodies:

- **High potency**. Izokibep binds both subunits of the IL-17A dimer simultaneously, resulting in complete blockade of IL-17 signaling in preclinical studies. Izokibep is highly potent with a dissociation constant (KD) of 0.3 pM to human IL-17A. Currently, FDA-approved anti-IL-17A agents secukinumab (marketed by Novartis AG) and ixekizumab (marketed by Eli Lilly and Company) have a KD of 200pM and 1.8 pM, respectively.

- **Albumin-binding domain provides half-life extension and broad tissue exposure**. The albumin-binding domain increases the plasma half-life of izokibep and enhances its ability to target sites of inflammation.

- **Small size drives robust tissue penetration**. Izokibep has a molecular weight of 18.6 kDa, approximately one-tenth the size of a monoclonal antibody, enabling the potential to reach difficult to penetrate tissues such as dense and poorly vascularized entheses in PsA and abscesses and inflammatory nodules in HS. In murine skin, izokibep demonstrated robust exposure, increasing over time, compared to secukinumab.

- **Potential to conveniently deliver high exposures**. The lower molecular weight of izokibep (18.6 kDa) compared to traditional monoclonal antibodies (~150 kDa) means that there are more izokibep drug molecules in a given volume. Additionally, as demonstrated in comparative analyses assessing binding affinity, izokibep molecules are also more potent than the currently marketed monoclonal antibodies targeting IL-17A, secukinumab and ixekizumab. We believe izokibep can deliver in a single subcutaneous injection exposure levels that the marketed anti-IL-17A monoclonal antibodies require IV infusion to deliver.

30. In addition, the Offering Documents contained the following statements regarding izokibep's purported efficacy in treating HS:

> Efficacy of treatments in HS is typically measured by improvements in Hidradenitis Suppurativa Clinical Response (HiSCR). HiSCR is a clinically validated scoring system that is used to assess disease activity and which was accepted as a valid clinical endpoint in the regulatory approval process for the only FDA-approved therapy for HS, adalimumab. HiSCR50 represents a 50% improvement in abscesses and inflammatory nodules without worsening in either of these individually or worsening in tunnelling; high order responses, such as 75% improvement (HiSCR75), 90% improvement (HiSCR90) and 100% improvement (HiSCR100, which means there are no abscesses or inflammatory nodules and no new fistulae/tunnels), represent even greater clinical responses on the reduction of inflammatory nodules and abscesses as well as fistulae/tunnels.
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> As presented at the 2023 American Academy of Dermatology (AAD) annual meeting, izokibep demonstrated high orders of HiSCR in Part A of our Phase 2b/3 trial in HS. Part A of this trial was designed to inform our own internal decision-making about the future of the izokibep development program in HS and consisted of open label treatment with izokibep 160 mg administered subcutaneously (SC) weekly (QW). Thirty participants were enrolled in the trial and nine discontinued for various reasons including physical relocation and lost to follow up (four), injection site reactions (three; two mild, one moderate), and serious adverse events (SAEs) relating to gastrointestinal symptoms (two). Of the two SAEs, one was Crohn's disease (potentially related) and the second was pre-existing diverticulitis with diverticular abscess and sepsis (not related). Our internal hurdle for continuing to advance development in HS was to see high orders of HiSCR responses. We have reported data as observed at 12 weeks with 71% of participants achieving HiSCR50, 57% achieving HiSCR75, 38% achieving HiSCR90 and 33% achieving HiSCR100. Both Hurley Stage II and III participants were present in the populations achieving the highest orders of response (HiSCR90 and HiSCR100).

31. Finally, in providing an overview of the Company's strategy, the Offering Documents stated, in relevant part:

Our vision is to build a leading integrated biopharma company focused on delivering transformative medicines to patients. Immunology is an area of deep core expertise throughout the organization, and therefore is our area of initial focus. Our mission is to identify, acquire, and accelerate the development and commercialization of medicines that we believe have the potential to offer clinically meaningful, differentiated benefits to patients. We intend to achieve that goal by implementing the following strategies.

- **Maximize the value of izokibep**. Izokibep is a "pipeline-in-a-program" with encouraging clinical data obtained in multiple immunology-related indications. We refer to izokibep as a "pipeline-in-a-program", which reflects our strategy to develop a single asset in multiple indications. Clinical data generated to date and the high in vitro potency and small molecular size of izokibep hold the potential for clinically meaningful responses in diseases such HS, PsA, AxSpA and uveitis, and we plan to advance these opportunities in parallel clinical trials. In addition, we intend to explore the potential development of izokibep in future indications where there is strong rationale for IL-17A inhibition and high unmet patient need.

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- **Diversify our portfolio with new product candidates**. Our ability to identify, acquire and rapidly advance izokibep into late-stage clinical trials across several indications exemplifies the approach that we are actively pursuing to continue to diversify our portfolio with drug candidates that fit our strategic focus. Specifically, we plan to acquire and advance new therapies where we feel we can offer unique experience and expertise to optimize their development and value.

- **Evaluate strategic collaborations**. We believe that our team's experience and track record demonstrate ACELYRIN's capabilities and make our company an attractive partner. We will strategically evaluate potential collaborations to maximize the value of our portfolio.

- **Build our operational and commercial capabilities for supplying and marketing our products, if approved, in key markets**. In general, we intend to manage our products from development through to commercialization. Where beneficial, we may collaborate with a partner for various capabilities such as manufacturing, marketing

and/or sales of our products in one or more geographies. With late-stage trials underway for izokibep in multiple indications, we remain committed to continuing to build the capabilities necessary to achieve our goal of becoming an integrated biopharma company.

32. On June 15, 2023, Acelyrin issued a press release announcing the Company's Q1 2023 financial results and recent highlights. The press release stated, in relevant part:

"The past several months have been transformative for ACELYRIN. We continue to work toward our mission to develop clinically meaningful, differentiated medicines by executing on development plans to test our hypotheses and determine how our assets might best address the significant unmet need that remains for patients across a multitude of autoimmune and inflammatory diseases," said [Defendant] Lin[.] "I am particularly pleased for patients that in the past six months we have been able to share izokibep data demonstrating resolution of important manifestations of disease and significant evidence of positive impact on quality of life. With the proceeds of our recent initial public offering, we will continue to drive towards key value-driving milestones to deliver efficiently on our development plans. We are pleased today to be sharing the acceleration of timing for top-line pivotal data for izokibep in Hidradenitis Suppurativa (HS), now expected in the third quarter of 2023, and that a second confirmatory Phase 3 trial in HS is now actively enrolling."

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Izokibep

In March, we shared as a late-breaking presentation at the 2023 American Academy of Dermatology (AAD) Annual Meeting data showing that treatment with izokibep led to high orders of HiSCR response at 12 weeks in the open label Part A of the Phase 2b/3 trial in HS. These responses included achieving HiSCR100, defined as complete resolution of abscesses and nodules with no new fistulae/draining tunnels, in moderate to severe patients representing both Hurley Stage II and III.

> Part B of the Phase 2b/3 trial completed enrollment early and top-line results are now anticipated in Q3 2023. An independent Data Monitoring Committee (DMC) conducted a planned interim analysis, reported no safety concerns, and confirmed 160mg weekly (QW) as the dose for the second Phase 3 trial in HS. This Phase 3 trial is now actively enrolling.
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> In April, we announced 46-week data from the Phase 2 trial of izokibep in Psoriatic Arthritis (PsA) showing that continued treatment of 80mg every two weeks (Q2W) led to further improvements beyond 16 weeks in magnitude of response across key manifestations of the disease including complete resolution of enthesitis in 89% of participants, PASI100 responses in 71% of participants, ACR50 responses in 79% of participants, and ACR70 responses in 50% of participants. A Phase 2b/3 trial in PsA is ongoing and includes further dose ranging up to 160mg QW.
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> The totality of evidence across these two independent datasets of HS and PsA continues to support the hypothesis that the high potency and small molecular size of izokibep can lead to clinically meaningful, differentiated benefits for patients, including resolution of important manifestations of each disease associated with residual pain and severity of disease.

33. That same day, Acelyrin filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operational results for the quarter ended March 31, 2023 (the "Q1 2023 10-Q"). The Q1 2023 10-Q stated, in relevant part:

> Our initial focus is on the treatment of diseases with pathology related to excess activation of the immune system, an area where our management and team bring industry-leading expertise. We acquired our portfolio of product candidates with the intent to develop and commercialize novel therapies that we believe may provide the opportunity to offer clinically meaningful, differentiated benefits for patients by improving upon the efficacy and/or safety of existing therapeutics directed against established targets, such as currently marketed anti-interleukin (IL)-17A agents, or by targeting new modalities. In each case, our strategy is to identify candidates we believe are "diamonds in the rough," where, based on molecule characteristics, our collective experience and expertise, and the evolving scientific and medical understanding, we can establish a clinical development plan that tests our hypotheses as to what those benefits could mean for

patients. Subsequently, we plan to utilize the results from initial clinical trials and the learnings we obtain from emerging biology to potentially expand the application of our candidates to other indications in which there are significant unmet needs.

* * *

Our lead product candidate is izokibep, a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity and the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody. Izokibep is currently in development for multiple immunological indications including [HS.]

34. Appended to the Q1 2023 10-Q as an exhibit was a signed certification pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by Defendants Lin and Dier, attesting that "the information contained in the [Q1 2023 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

35. On August 14, 2023, Acelyrin issued a press release announcing the Company's Q2 2023 financial results and recent highlights. The press release stated, in relevant part:

"The first half of 2023 has been productive and rewarding as we marked a number of clinical and corporate milestones supporting our mission to identify, acquire and accelerate the development and commercialization of transformative medicines for patients," said [Defendant] Lin[.] "From our successful initial public offering in May to our continued clinical progress across the portfolio including izokibep, lonigutamab and SLRN-517, we are aggressively executing against our plans for the potential to accelerate better treatment options for patients and value for shareholders. We're very pleased to share today new data from Part A of the Phase 2b/3 trial of izokibep in Hidradenitis Suppurativa, or HS, demonstrating that the majority of patients are achieving improvements in the number of draining tunnels within the first month of therapy. The totality of evidence across our HS and Psoriatic Arthritis trial results continues to support the hypothesis that the high potency

and small molecular size of izokibep can lead to clinically meaningful, differentiated benefits for patients, including resolution of important manifestations of each disease that otherwise lead to pain, disability and poorer overall quality of life."

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Recent Highlights and Upcoming Milestones

Izokibep

Izokibep is a small protein therapeutic designed to inhibit IL-17A with high potency and small molecular size, approximately 1/10th the size of a monoclonal antibody. Our recent data in Hidradenitis Suppurativa (HS) and Psoriatic Arthritis (PsA) demonstrate – in two independent data sets across two indications – the potential for resolution of disease in difficult-to-treat tissues, and that improves over time. Trials designed for the potential to be part of registrational packages are underway in moderate-to-severe HS, PsA and uveitis, with plans to initiate an additional Phase 3 program in axial spondyloarthritis (AxSpA).

- A new analysis from Part A of the Phase 2b/3 trial in HS suggests that treatment with izokibep results in improvement of at least one draining tunnel as early as week 4 in two-thirds of continuing patients. Week 4 was the first timepoint assessed and this result remained consistent through week 12. Furthermore, half of continuing patients improved by at least two draining tunnels by week 8 and remained consistent through week 12. The speed of response, as well as the magnitude of response at the later time points, is a promising development. It is important to note that this analysis is based off a small dataset with numbers of patients in the high single digit to low double digits. Additional understanding of izokibep's impact on draining tunnels will be informed by the Part B data set.

    - Enrollment of the double-blind, placebo-controlled Part B of the Phase 2b/3 trial evaluating izokibep in HS completed ahead of schedule, accelerating anticipated top-line results into the third quarter 2023.

- Based on the results seen in the open-label Part A of the trial as presented at AAD in March 2023, we remain focused on resolution of

disease as approximated by high orders of response such as HiSCR100. HiSCR100 is a stringent measure of disease control in HS as it requires the same individual to achieve both abscess/nodule resolution without formation of new draining tunnels. We believe that full control of active inflammation enables the early improvements observed in the number of draining tunnels in Part A.

- Also during the quarter, an independent Data Monitoring Committee (DMC) conducted a pre-planned review of unblinded efficacy and safety data from Part B of the P2b/3 trial in HS and confirmed the dose of 160mg QW for the second Phase 3 trial in HS. While the company remains blinded to the data, this confirmation is consistent with the understanding that higher exposures are required in HS and aligns with our hypothesis that the high potency and small size of izokibep could lead to clinically meaningful differentiated benefits.

    - With the dose confirmed in May, we dosed the first patient in the second HS Phase 3 trial in June, and that trial continues to actively enroll.

- In April, the Company reported 46-week results from the Phase 2 trial in PsA that showed continued, deepening improvements beyond 16 weeks across key manifestations of the disease. Of participants receiving izokibep 80 mg Q2W, 79% achieved ACR50 response versus 52% at week 16 and even higher measures of clinical response – including significant control or resolution of disease – were observed with 50% achieving ACR70 response, 71% achieving PASI100 response, and 89% achieving enthesitis resolution. This was predicted by internal modeling that suggested the magnitude of clinical response would continue to increase with longer duration of treatment. The model also predicts further differentiation may be achieved with increasing dose levels, which we are testing in the ongoing Phase 2b/3 trial in PsA.

    - Enrollment in the PsA Phase 2b/3 trial has been completed, and top-line results are now anticipated to be accelerated into first quarter 2024 from mid-2024.

- A Phase 2b/3 trial evaluating izokibep in uveitis is enrolling. Previously reported data for secukinumab have validated the inhibition of IL-17A

in uveitis by demonstrating a clinical response with IV levels of exposure. Izokibep can achieve secukinumab IV level exposures with a single subcutaneous injection. This provides the potential to unlock inhibition of IL-17A as an approach to treating uveitis where significant unmet need remains.

- The Company also plans to initiate a Phase 3 program to evaluate izokibep for the treatment of AxSpA in 2024. Enthesitis is a central feature of AxSpA, and we believe the rates of enthesitis resolution demonstrated in the Phase 2 PsA trial suggest the potential for clinically meaningful, differentiated benefits for patients with this disease.

36. That same day, Acelyrin filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operational results for the quarter ended June 30, 2023 (the "Q2 2023 10-Q"). The Q2 2023 10-Q contained substantively similar statements as referenced in ¶ 33, *supra*, regarding izokibep's purported mechanism of action in treating diseases such as HS.

37. Appended to the Q2 2023 10-Q as an exhibit was a signed certification pursuant to SOX by Defendants Lin and Labrucherie, attesting that "the information contained in the [Q2 2023 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

38. On August 16, 2023, Acelyrin hosted an earnings call with investors and analysts to discuss the Company's Q2 2023 results (the "Q2 2023 Earnings Call"). During the scripted portion of the Q2 2023 Earnings Call, Defendant Lin stated, in relevant part:

> Since our founding in 2020, we have created a robust portfolio. This includes our lead program, izokibep, which is a small therapeutic protein whose high potency and small molecular size we believe can drive clinically meaningful

differentiated benefit for patients across multiple indications, truly a potential pipeline and a program.

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Recall that izokibep is a small protein therapeutic designed to inhibit IL-17A with high potency through tight binding affinity, the potential for robust tissue penetration due to its small molecular size, about one-tenth the size of a monoclonal antibody, and an albumin-binding domain that extends half-life. And we have hypothesized that this high potency and small size can lead to clinically meaningful differences in efficacy relative to the market in monoclonal antibodies against this target and without the introduction of new safety liabilities. We are pursuing late-stage development of izokibep across a number of indications where IL-17A inhibition has been validated. These include HS, PsA, uveitis, and axial spondyloarthritis.

Let me begin with the progress we've made with our HS program. HS is a chronic inflammatory disease characterized by skin abscesses, inflammatory nodules, draining tunnels, scar tissue, malodor, and pain, often resulting in permanent disfigurement and social stigma, and all of this contributing to poor quality of life. HS affects more than 300,000 patients in the U.S. with more than half of these patients considered moderate to severe.

There is currently only one FDA-approved treatment for HS, and a significant need remains for new medicines that provide more rapid and complete resolution of the disease. We've long known that drug exposures in HS are lower compared to other inflammatory conditions and had hypothesized that the high potency of izokibep on two IL-17A, as well as a small molecular size, again about a tenth of the size of a monoclonal antibody, could generate deep levels of clinical response due to robust tissue penetration and potent target engagement.

39. The statements referenced in ¶¶ 28-38 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose

that: (i) izokibep was less effective in treating HS than Defendants had led investors to believe; (ii) accordingly, Acelyrin overstated izokibep's clinical and/or commercial prospects; (iii) as a result, Acelyrin also overstated the Company's business prospects post-IPO; and (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

40. On September 11, 2023, after the markets closed, Acelyrin issued a press release entitled "ACELYRIN, INC. Announces Top-Line Results from Placebo-Controlled Clinical Trial of Izokibep for Moderate-to-Severe Hidradenitis Suppurativa." The press release stated, in relevant part:

> ACELYRIN [. . .] today announced top-line results from Part B of a Phase 2b/3 trial evaluating izokibep for the treatment of moderate-to-severe Hidradenitis Suppurativa (HS). The primary endpoint of HiSCR75 at week 16 did not meet statistical significance. However, response rates for izokibep showed early HiSCR100 responses, a clear dose-effect supported by both pharmacokinetic exposures and HiSCR responses favoring 160mg weekly dosing, and no evidence of safety or tolerability limitation.
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> "First, I would like to thank the patients and clinicians in this study, without whom we would not be able to continue to learn about how best to treat this debilitating disease. Although the overall study did not meet statistical significance, izokibep appears to be demonstrating consistent early and high orders of response for patients suffering from hidradenitis suppurativa without safety or tolerability limitation," said Shao-Lee Lin, MD, PhD, founder and CEO of ACELYRIN. "The consistent and early achievement of HiSCR100, along with our prior izokibep experience in Psoriatic Arthritis, continues to demonstrate the potential of izokibep for resolution of disease, especially in difficult to treat tissues. These results further support our ongoing evaluations of 160 mg QW dosing in HS, as well as for additional indications, including uveitis and PsA, the largest potential indication for izokibep."

The randomized double-blind, placebo-controlled, multi-center trial evaluated the safety and efficacy of izokibep dosed 160 mg weekly (QW) and every two weeks (Q2W), versus placebo, in 175 patients with moderate-to-severe HS (Hurley Stage II and III). The trial was conducted at 50 sites globally and assessed various efficacy endpoints, including the primary endpoint of HiSCR75 (Hidradenitis Suppurativa Clinical Response) at 16 weeks utilizing a non-responder imputation (NRI) analysis method.

In the primary NRI analysis of Part B, statistical significance was impacted by patients with HiSCR75-100 discontinuing as early as week 4 unrelated to adverse events. In addition, there was a marked increase in placebo rates during the course of the study. Applying a Last Observation Carried Forward (LOCF) sensitivity analysis of the full dataset highlighted the impact of responder discontinuations on the primary analysis and showed statistical significance of HiSCR75 at week 16.

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An independently conducted pre-planned interim analysis, to which the company remained blinded until the time of this primary analysis, occurred prior to a rise in placebo rates observed later in the trial. This dataset provides an opportunity to view the performance of izokibep prior to this increase. The table below shows the consistency of Part A open label results relative to the Part B placebo-controlled interim analysis, which was pre-specified to be an as observed analysis at week 12.

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Also, given the number of responders who discontinued in the QW arm – the majority unrelated to an adverse event – a modified-NRI (mNRI) approach showed a high level of statistical significance and highlighted the impact of discontinuations on magnitude and significance of response. This analysis demonstrates the performance of izokibep at this juncture in the study – in isolation from the placebo rate increases observed later in the trial – and provides an exploratory approach to analyzing responder discontinuations.

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The safety profile for izokibep was consistent with prior studies and the anti-IL-17A class. There were no events of candida in the high dose 160mg QW

arm and there were two discontinuations across the trial due to injection site reactions (3.5%).

41. On this news, Acelyrin's stock price fell $17.19 per share, or 61.61%, over the following two trading sessions, to close at $10.71 per share on September 13, 2023.

42. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of Acelyrin's securities, Plaintiff and other Class members have suffered significant losses and damages.

SCIENTER ALLEGATIONS

43. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices, and participated in a course of business that operated as a fraud or deceit on purchasers of the Company's securities during the Class Period.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

44. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Acelyrin securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant

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

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

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

47. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

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

- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Acelyrin;

- whether the Individual Defendants caused Acelyrin to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Acelyrin securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

49. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

50. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- Acelyrin securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold Acelyrin securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

51. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

52. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

53. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

54. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

55. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Acelyrin securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Acelyrin securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

56. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Acelyrin securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to

disclose material adverse information and misrepresented the truth about Acelyrin's finances and business prospects.

57. By virtue of their positions at Acelyrin, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

58. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Acelyrin, the Individual Defendants had knowledge of the details of Acelyrin's internal affairs.

59. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Acelyrin. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information

with respect to Acelyrin's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Acelyrin securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Acelyrin's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Acelyrin securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

60. During the Class Period, Acelyrin securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Acelyrin securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Acelyrin securities was substantially lower than the prices paid by Plaintiff and the other

members of the Class. The market price of Acelyrin securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

61. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

62. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

63. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

64. During the Class Period, the Individual Defendants participated in the operation and management of Acelyrin, and conducted and participated, directly and indirectly, in the conduct of Acelyrin's business affairs. Because of their senior positions, they knew the adverse non-public information about Acelyrin's misstatement of income and expenses and false financial statements.

65. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Acelyrin's financial condition and results of operations, and to correct promptly any public statements issued by Acelyrin which had become materially false or misleading.

66. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Acelyrin disseminated in the marketplace during the Class Period concerning Acelyrin's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Acelyrin to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Acelyrin within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Acelyrin securities.

67. Each of the Individual Defendants, therefore, acted as a controlling person of Acelyrin. By reason of their senior management positions and/or being directors of Acelyrin, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Acelyrin to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Acelyrin and possessed the power to control the specific activities

which comprise the primary violations about which Plaintiff and the other members of the Class complain.

68. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Acelyrin.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.