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UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

, Individually  
and On Behalf of All Others Similarly  
Situated,  
  
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*

1 *alia*, the investigation conducted by and through Plaintiff’s attorneys, which included,  
2 among other things, a review of the Defendants’ public documents, conference calls and  
3 announcements made by Defendants, United States (“U.S.”) Securities and Exchange  
4 Commission (“SEC”) filings, wire and press releases published by and regarding  
5 ACELYRIN, Inc. (“Acelyrin” or the “Company”), analysts’ reports and advisories about  
6 the Company, and information readily obtainable on the Internet. Plaintiff believes that  
7 substantial, additional evidentiary support will exist for the allegations set forth herein  
8 after a reasonable opportunity for discovery.

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12 **NATURE OF THE ACTION**

13  
14 1. This is a federal securities class action on behalf of a class consisting of all  
15 persons and entities other than Defendants that purchased or otherwise acquired Acelyrin  
16 securities between May 4, 2023 and September 11, 2023, both dates inclusive (the “Class  
17 Period”). Plaintiff pursues claims against the Defendants under the Securities Exchange  
18 Act of 1934 (the “Exchange Act”).

19  
20 2. Acelyrin is a clinical biopharma company that focuses on developing and  
21 commercializing transformative medicines. The Company’s lead product candidate is  
22 izokibep, a small protein therapeutic designed to inhibit IL-17A with purportedly high  
23 potency, which is currently in Part B of a Phase 2b/3 clinical trial for use in the treatment  
24 of moderate to severe Hidradenitis Suppurativa (“HS”).  
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1           3.     On April 13, 2023, Acelyrin filed a registration statement on Form S-1 with  
2 the SEC in connection with the Company’s Initial Public Offering (“IPO”), which, after  
3 several amendments, was declared effective by the SEC on May 4, 2023 (the “Registration  
4 Statement”).  
5

6           4.     On May 4, 2023, pursuant to the Registration Statement, Acelyrin’s common  
7 stock began publicly trading on the Nasdaq Global Select Market (“NASDAQ”) under the  
8 trading symbol “SLRN”.  
9

10          5.     On May 5, 2023, Acelyrin filed a prospectus on Form 424B4 with the SEC  
11 in connection with the IPO, which incorporated and formed part of the Registration  
12 Statement (the “Prospectus” and, collectively with the Registration Statement, the  
13 “Offering Documents”).  
14

15          6.     Pursuant to the Offering Documents, Acelyrin issued 30 million shares of its  
16 common stock to the public at the Offering price of \$18.00 per share for proceeds to the  
17 Company of \$502.2 million after applicable underwriting discounts and commissions.  
18

19          7.     Throughout the Class Period, Defendants made materially false and  
20 misleading statements regarding the Company’s business, operations, and prospects.  
21 Specifically, Defendants made false and/or misleading statements and/or failed to disclose  
22 that: (i) izokibep was less effective in treating HS than Defendants had led investors to  
23 believe; (ii) accordingly, Acelyrin overstated izokibep’s clinical and/or commercial  
24 prospects; (iii) as a result, Acelyrin also overstated the Company’s business prospects  
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1 post-IPO; and (iv) as a result, the Company's public statements were materially false and  
2 misleading at all relevant times.

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

9  
10  
11 9. On this news, Acelyrin's stock price fell \$17.19 per share, or 61.61%, over  
12 the following two trading sessions, to close at \$10.71 per share on September 13, 2023.

13  
14 10. As a result of Defendants' wrongful acts and omissions, and the precipitous  
15 decline in the market value of Acelyrin's securities, Plaintiff and other Class members  
16 have suffered significant losses and damages.

17  
18 **JURISDICTION AND VENUE**

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

22  
23 12. This Court has jurisdiction over the subject matter of this action pursuant to  
24 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

25  
26 13. Venue is proper in this Judicial District pursuant to Section 27 of the  
27 Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Acelyrin is headquartered in  
28

1 this Judicial District, Defendants conduct business in this Judicial District, and a  
2 significant portion of Defendants’ activities took place within this Judicial District.  
3

4 14. In connection with the acts alleged in this Complaint, Defendants, directly  
5 or indirectly, used the means and instrumentalities of interstate commerce, including, but  
6 not limited to, the mails, interstate telephone communications, and the facilities of the  
7 national securities markets.  
8

9 **PARTIES**

10  
11 15. Plaintiff, as set forth in the attached Certification, acquired Acelyrin  
12 securities at artificially inflated prices during the Class Period and suffered damages as a  
13 result of the federal securities law violations and false and/or misleading statements  
14 and/or material omissions alleged herein.  
15

16 16. Defendant Acelyrin is a Delaware corporation with principal executive  
17 offices located at 4149 Liberty Canyon Road, Agoura Hills, California 91301. The  
18 Company’s common stock trades in an efficient market on the NASDAQ under the trading  
19 symbol “SLRN”.  
20  
21

22 17. Defendant Shao-Lee Lin (“Lin”) has served as Acelyrin’s Founder, Chief  
23 Executive Officer, and a Director of the Company at all relevant times.  
24

25 18. Defendant Mardi C. Dier (“Dier”) served as Acelyrin’s Chief Financial  
26 Officer (“CFO”) and Chief Business Officer from before the start of the Class Period to  
27 August 15, 2023.  
28

1 19. Defendant Gil Labrucherie (“Labrucherie”) has served as Acelyrin’s CFO  
2 since August 15, 2023.

3  
4 20. Defendants Lin, Dier, and Labrucherie are sometimes referred to herein  
5 collectively as the “Individual Defendants”.

6  
7 21. The Individual Defendants possessed the power and authority to control the  
8 contents of Acelyrin’s SEC filings, press releases, and other market communications. The  
9 Individual Defendants were provided with copies of Acelyrin’s SEC filings and press  
10 releases alleged herein to be misleading prior to or shortly after their issuance and had the  
11 ability and opportunity to prevent their issuance or to cause them to be corrected. Because  
12 of their positions with Acelyrin, and their access to material information available to them  
13 but not to the public, the Individual Defendants knew that the adverse facts specified  
14 herein had not been disclosed to and were being concealed from the public, and that the  
15 positive representations being made were then materially false and misleading. The  
16 Individual Defendants are liable for the false statements and omissions pleaded herein.  
17  
18  
19

20 22. Acelyrin and the Individual Defendants are sometimes referred to herein  
21 collectively as the “Defendants”.  
22

23 **SUBSTANTIVE ALLEGATIONS**

24 **Background**

25  
26 23. Acelyrin is a clinical biopharma company that focuses on identifying,  
27 acquiring, and accelerating the development and commercialization of transformative  
28

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

5 24. On April 13, 2023, Acelyrin filed the Registration Statement on Form S-1  
6 with the SEC in connection with the IPO, which, after several amendments, was declared  
7  
8 effective by the SEC on May 4, 2023.

9 25. On May 4, 2023, pursuant to the Registration Statement, Acelyrin's common  
10  
11 stock began publicly trading on the NASDAQ under the trading symbol "SLRN".

12 26. On May 5, 2023, Acelyrin filed the Prospectus on Form 424B4 with the SEC  
13  
14 in connection with the IPO, which incorporated and formed part of the Registration  
15  
16 Statement.

17 27. Pursuant to the Offering Documents, Acelyrin issued 30 million shares of its  
18  
19 common stock to the public at the Offering price of \$18.00 per share for proceeds to the  
20  
21 Company of \$502.2 million after applicable underwriting discounts and commissions.

22 **Materially False and Misleading Statements Issued During the Class Period**

23 28. The Class Period begins on May 4, 2023, when Acelyrin's common stock  
24  
25 began publicly trading on the NASDAQ pursuant to the materially false or misleading  
26  
27 statements or omissions in the Offering Documents. For example, in providing an  
28  
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

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

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

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

## 24 **Our Pipeline**

25 Our lead product candidate is izokibep, a small protein therapeutic  
26 designed to inhibit IL-17A with high potency through tight binding affinity  
27 and the potential for robust tissue penetration due to its small molecular size,  
28 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



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

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

- 6 • **High potency.** Izokibep binds both subunits of the IL-17A dimer  
7 simultaneously, resulting in complete blockade of IL-17 signaling in  
8 preclinical studies. Izokibep is highly potent with a dissociation  
9 constant (KD) of 0.3 pM to human IL-17A. Currently, FDA-approved  
10 anti-IL-17A agents secukinumab (marketed by Novartis AG) and  
11 ixekizumab (marketed by Eli Lilly and Company) have a KD of 200pM  
12 and 1.8 pM, respectively.
- 13 • **Albumin-binding domain provides half-life extension and broad  
14 tissue exposure.** The albumin-binding domain increases the plasma  
15 half-life of izokibep and enhances its ability to target sites of  
16 inflammation.
- 17 • **Small size drives robust tissue penetration.** Izokibep has a molecular  
18 weight of 18.6 kDa, approximately one-tenth the size of a monoclonal  
19 antibody, enabling the potential to reach difficult to penetrate tissues  
20 such as dense and poorly vascularized entheses in PsA and abscesses  
21 and inflammatory nodules in HS. In murine skin, izokibep  
22 demonstrated robust exposure, increasing over time, compared to  
23 secukinumab.
- 24 • **Potential to conveniently deliver high exposures.** The lower  
25 molecular weight of izokibep (18.6 kDa) compared to traditional  
26 monoclonal antibodies (~150 kDa) means that there are more izokibep  
27 drug molecules in a given volume. Additionally, as demonstrated in  
28 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.

1           30.     In addition, the Offering Documents contained the following statements  
2 regarding izokibep’s purported efficacy in treating HS:  
3

4           Efficacy of treatments in HS is typically measured by improvements  
5 in Hidradenitis Suppurativa Clinical Response (HiSCR). HiSCR is a clinically  
6 validated scoring system that is used to assess disease activity and which was  
7 accepted as a valid clinical endpoint in the regulatory approval process for the  
8 only FDA-approved therapy for HS, adalimumab. HiSCR50 represents a 50%  
9 improvement in abscesses and inflammatory nodules without worsening in  
10 either of these individually or worsening in tunnelling; high order responses,  
11 such as 75% improvement (HiSCR75), 90% improvement (HiSCR90) and  
12 100% 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.

13           As presented at the 2023 American Academy of Dermatology (AAD)  
14 annual meeting, izokibep demonstrated high orders of HiSCR in Part A of our  
15 Phase 2b/3 trial in HS. Part A of this trial was designed to inform our own  
16 internal decision-making about the future of the izokibep development  
17 program in HS and consisted of open label treatment with izokibep 160 mg  
18 administered subcutaneously (SC) weekly (QW). Thirty participants were  
19 enrolled in the trial and nine discontinued for various reasons including  
20 physical relocation and lost to follow up (four), injection site reactions (three;  
21 two mild, one moderate), and serious adverse events (SAEs) relating to  
22 gastrointestinal symptoms (two). Of the two SAEs, one was Crohn’s disease  
23 (potentially related) and the second was pre-existing diverticulitis with  
24 diverticular abscess and sepsis (not related). Our internal hurdle for continuing  
25 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).

26           31.     Finally, in providing an overview of the Company’s strategy, the Offering  
27 Documents stated, in relevant part:  
28

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

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

19 \*\*\*

- 20 • **Diversify our portfolio with new product candidates.** Our ability to  
21 identify, acquire and rapidly advance izokibep into late-stage clinical  
22 trials across several indications exemplifies the approach that we are  
23 actively pursuing to continue to diversify our portfolio with drug  
24 candidates that fit our strategic focus. Specifically, we plan to acquire  
25 and advance new therapies where we feel we can offer unique  
26 experience and expertise to optimize their development and value.
- 27 • **Evaluate strategic collaborations.** We believe that our team’s  
28 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

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

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

8  
9 "The past several months have been transformative for ACELYRIN. We  
10 continue to work toward our mission to develop clinically meaningful,  
11 differentiated medicines by executing on development plans to test our  
12 hypotheses and determine how our assets might best address the significant  
13 unmet need that remains for patients across a multitude of autoimmune and  
14 inflammatory diseases," said [Defendant] Lin[.] "I am particularly pleased for  
15 patients that in the past six months we have been able to share izokibep data  
16 demonstrating resolution of important manifestations of disease and  
17 significant evidence of positive impact on quality of life. With the proceeds  
18 of our recent initial public offering, we will continue to drive towards key  
19 value-driving milestones to deliver efficiently on our development plans. We  
20 are pleased today to be sharing the acceleration of timing for top-line pivotal  
21 data for izokibep in Hidradenitis Suppurativa (HS), now expected in the third  
22 quarter of 2023, and that a second confirmatory Phase 3 trial in HS is now  
23 actively enrolling."

24 \*\*\*

25 ***Izokibep***

26 In March, we shared as a late-breaking presentation at the 2023 American  
27 Academy of Dermatology (AAD) Annual Meeting data showing that  
28 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.

1 Part B of the Phase 2b/3 trial completed enrollment early and top-line results  
2 are now anticipated in Q3 2023. An independent Data Monitoring Committee  
3 (DMC) conducted a planned interim analysis, reported no safety concerns,  
4 and confirmed 160mg weekly (QW) as the dose for the second Phase 3 trial  
5 in HS. This Phase 3 trial is now actively enrolling.

6 In April, we announced 46-week data from the Phase 2 trial of izokibep in  
7 Psoriatic Arthritis (PsA) showing that continued treatment of 80mg every two  
8 weeks (Q2W) led to further improvements beyond 16 weeks in magnitude of  
9 response across key manifestations of the disease including complete  
10 resolution of enthesitis in 89% of participants, PASI100 responses in 71% of  
11 participants, ACR50 responses in 79% of participants, and ACR70 responses  
12 in 50% of participants. A Phase 2b/3 trial in PsA is ongoing and includes  
13 further dose ranging up to 160mg QW.

14 The totality of evidence across these two independent datasets of HS and PsA  
15 continues to support the hypothesis that the high potency and small molecular  
16 size of izokibep can lead to clinically meaningful, differentiated benefits for  
17 patients, including resolution of important manifestations of each disease  
18 associated with residual pain and severity of disease.

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

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

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

5 \* \* \*

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

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

15 35. On August 14, 2023, Acelyrin issued a press release announcing the  
16 Company’s Q2 2023 financial results and recent highlights. The press release stated, in  
17 relevant part:  
18

19 “The first half of 2023 has been productive and rewarding as we marked a  
20 number of clinical and corporate milestones supporting our mission to  
21 identify, acquire and accelerate the development and commercialization of  
22 transformative medicines for patients,” said [Defendant] Lin[.] “From our  
23 successful initial public offering in May to our continued clinical progress  
24 across the portfolio including izokibep, lonigutamab and SLRN-517, we are  
25 aggressively executing against our plans for the potential to accelerate better  
26 treatment options for patients and value for shareholders. We’re very pleased  
27 to share today new data from Part A of the Phase 2b/3 trial of izokibep in  
28 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

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

5 \*\*\*

## 6 **Recent Highlights and Upcoming Milestones**

### 7 *Izokibep*

8 Izokibep is a small protein therapeutic designed to inhibit IL-17A with high  
9 potency and small molecular size, approximately 1/10th the size of a  
10 monoclonal antibody. Our recent data in Hidradenitis Suppurativa (HS) and  
11 Psoriatic Arthritis (PsA) demonstrate – in two independent data sets across  
12 two indications – the potential for resolution of disease in difficult-to-treat  
13 tissues, and that improves over time. Trials designed for the potential to be  
14 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).

- 15 • A new analysis from Part A of the Phase 2b/3 trial in HS suggests that  
16 treatment with izokibep results in improvement of at least one draining  
17 tunnel as early as week 4 in two-thirds of continuing patients. Week 4  
18 was the first timepoint assessed and this result remained consistent  
19 through week 12. Furthermore, half of continuing patients improved by  
20 at least two draining tunnels by week 8 and remained consistent through  
21 week 12. The speed of response, as well as the magnitude of response  
22 at the later time points, is a promising development. It is important to  
23 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.
  - 24 ○ Enrollment of the double-blind, placebo-controlled Part B of the  
25 Phase 2b/3 trial evaluating izokibep in HS completed ahead of  
26 schedule, accelerating anticipated top-line results into the third  
27 quarter 2023.
- 28 • 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

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

- 7 • Also during the quarter, an independent Data Monitoring Committee  
8 (DMC) conducted a pre-planned review of unblinded efficacy and  
9 safety data from Part B of the P2b/3 trial in HS and confirmed the dose  
10 of 160mg QW for the second Phase 3 trial in HS. While the company  
11 remains blinded to the data, this confirmation is consistent with the  
12 understanding that higher exposures are required in HS and aligns with  
13 our hypothesis that the high potency and small size of izokibep could  
14 lead to clinically meaningful differentiated benefits.
  - 15 ○ With the dose confirmed in May, we dosed the first patient in the  
16 second HS Phase 3 trial in June, and that trial continues to  
17 actively enroll.
- 18 • In April, the Company reported 46-week results from the Phase 2 trial  
19 in PsA that showed continued, deepening improvements beyond 16  
20 weeks across key manifestations of the disease. Of participants  
21 receiving izokibep 80 mg Q2W, 79% achieved ACR50 response versus  
22 52% at week 16 and even higher measures of clinical response –  
23 including significant control or resolution of disease – were observed  
24 with 50% achieving ACR70 response, 71% achieving PASI100  
25 response, and 89% achieving enthesitis resolution. This was predicted  
26 by internal modeling that suggested the magnitude of clinical response  
27 would continue to increase with longer duration of treatment. The  
28 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



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

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

9  
10 36. That same day, Acelyrin filed a Quarterly Report on Form 10-Q with the  
11 SEC, reporting the Company's financial and operational results for the quarter ended June  
12 30, 2023 (the "Q2 2023 10-Q"). The Q2 2023 10-Q contained substantively similar  
13 statements as referenced in ¶ 33, *supra*, regarding izokibep's purported mechanism of  
14 action in treating diseases such as HS.

15  
16 37. Appended to the Q2 2023 10-Q as an exhibit was a signed certification  
17 pursuant to SOX by Defendants Lin and Labrucherie, attesting that "the information  
18 contained in the [Q2 2023 10-Q] fairly presents, in all material respects, the financial  
19 condition and results of operations of the Company."

20  
21  
22 38. On August 16, 2023, Acelyrin hosted an earnings call with investors and  
23 analysts to discuss the Company's Q2 2023 results (the "Q2 2023 Earnings Call"). During  
24 the scripted portion of the Q2 2023 Earnings Call, Defendant Lin stated, in relevant part:

25  
26 Since our founding in 2020, we have created a robust portfolio. This includes  
27 our lead program, izokibep, which is a small therapeutic protein whose high  
28 potency and small molecular size we believe can drive clinically meaningful

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

3 \*\*\*

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

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

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

28 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

1 that: (i) izokibep was less effective in treating HS than Defendants had led investors to  
2 believe; (ii) accordingly, Acelyrin overstated izokibep’s clinical and/or commercial  
3 prospects; (iii) as a result, Acelyrin also overstated the Company’s business prospects  
4 post-IPO; and (iv) as a result, the Company’s public statements were materially false and  
5 misleading at all relevant times.  
6  
7

### 8 The Truth Emerges

9 40. On September 11, 2023, after the markets closed, Acelyrin issued a press  
10 release entitled “ACELYRIN, INC. Announces Top-Line Results from Placebo-  
11 Controlled Clinical Trial of Izokibep for Moderate-to-Severe Hidradenitis Suppurativa.”  
12

13 The press release stated, in relevant part:  
14

15 ACELYRIN [. . .] today announced top-line results from Part B of a Phase  
16 2b/3 trial evaluating izokibep for the treatment of moderate-to-severe  
17 Hidradenitis Suppurativa (HS). The primary endpoint of HiSCR75 at week 16  
18 did not meet statistical significance. However, response rates for izokibep  
19 showed early HiSCR100 responses, a clear dose-effect supported by both  
20 pharmacokinetic exposures and HiSCR responses favoring 160mg weekly  
21 dosing, and no evidence of safety or tolerability limitation.

22 “First, I would like to thank the patients and clinicians in this study, without  
23 whom we would not be able to continue to learn about how best to treat this  
24 debilitating disease. Although the overall study did not meet statistical  
25 significance, izokibep appears to be demonstrating consistent early and high  
26 orders of response for patients suffering from hidradenitis suppurativa without  
27 safety or tolerability limitation,” said Shao-Lee Lin, MD, PhD, founder and  
28 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.”

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

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

14 \*\*\*

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

22 \*\*\*

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

\*\*\*

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

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

3 41. On this news, Acelyrin’s stock price fell \$17.19 per share, or 61.61%, over  
4 the following two trading sessions, to close at \$10.71 per share on September 13, 2023.  
5

6 42. As a result of Defendants’ wrongful acts and omissions, and the precipitous  
7 decline in the market value of Acelyrin’s securities, Plaintiff and other Class members  
8 have suffered significant losses and damages.  
9

### 10 **SCIENTER ALLEGATIONS**

11 43. During the Class Period, Defendants had both the motive and opportunity to  
12 commit fraud. They also had actual knowledge of the misleading nature of the statements  
13 they made, or acted in reckless disregard of the true information known to them at the  
14 time. In so doing, Defendants participated in a scheme to defraud and committed acts,  
15 practices, and participated in a course of business that operated as a fraud or deceit on  
16 purchasers of the Company’s securities during the Class Period.  
17  
18

### 19 **PLAINTIFF’S CLASS ACTION ALLEGATIONS**

20 44. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil  
21 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or  
22 otherwise acquired Acelyrin securities during the Class Period (the “Class”); and were  
23 damaged upon the revelation of the alleged corrective disclosures. Excluded from the  
24 Class are Defendants herein, the officers and directors of the Company, at all relevant  
25  
26  
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28

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

3  
4 45. The members of the Class are so numerous that joinder of all members is  
5 impracticable. Throughout the Class Period, Acelyrin securities were actively traded on  
6 the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this  
7 time and can be ascertained only through appropriate discovery, Plaintiff believes that  
8 there are hundreds or thousands of members in the proposed Class. Record owners and  
9 other members of the Class may be identified from records maintained by Acelyrin or its  
10 transfer agent and may be notified of the pendency of this action by mail, using the form  
11 of notice similar to that customarily used in securities class actions.  
12  
13  
14

15 46. Plaintiff's claims are typical of the claims of the members of the Class as all  
16 members of the Class are similarly affected by Defendants' wrongful conduct in violation  
17 of federal law that is complained of herein.  
18

19 47. Plaintiff will fairly and adequately protect the interests of the members of the  
20 Class and has retained counsel competent and experienced in class and securities litigation.  
21 Plaintiff has no interests antagonistic to or in conflict with those of the Class.  
22

23 48. Common questions of law and fact exist as to all members of the Class and  
24 predominate over any questions solely affecting individual members of the Class. Among  
25 the questions of law and fact common to the Class are:  
26

- 27  
28
- whether the federal securities laws were violated by Defendants' acts as alleged herein;

- 1 • whether statements made by Defendants to the investing public during the  
2 Class Period misrepresented material facts about the business, operations  
3 and management of Acelyrin;
- 4 • whether the Individual Defendants caused Acelyrin to issue false and  
5 misleading financial statements during the Class Period;
- 6 • whether Defendants acted knowingly or recklessly in issuing false and  
7 misleading financial statements;
- 8 • whether the prices of Acelyrin securities during the Class Period were  
9 artificially inflated because of the Defendants' conduct complained of  
10 herein; and
- 11 • whether the members of the Class have sustained damages and, if so, what  
12 is the proper measure of damages.

13 49. A class action is superior to all other available methods for the fair and  
14 efficient adjudication of this controversy since joinder of all members is impracticable.  
15 Furthermore, as the damages suffered by individual Class members may be relatively  
16 small, the expense and burden of individual litigation make it impossible for members of  
17 the Class to individually redress the wrongs done to them. There will be no difficulty in  
18 the management of this action as a class action.  
19  
20

21 50. Plaintiff will rely, in part, upon the presumption of reliance established by the  
22 fraud-on-the-market doctrine in that:  
23

- 24 • Defendants made public misrepresentations or failed to disclose material  
25 facts during the Class Period;
- 26 • the omissions and misrepresentations were material;
- 27 • Acelyrin securities are traded in an efficient market;
- 28





1           55. During the Class Period, Defendants engaged in a plan, scheme, conspiracy  
2 and course of conduct, pursuant to which they knowingly or recklessly engaged in acts,  
3 transactions, practices and courses of business which operated as a fraud and deceit upon  
4 Plaintiff and the other members of the Class; made various untrue statements of material  
5 facts and omitted to state material facts necessary in order to make the statements made,  
6 in light of the circumstances under which they were made, not misleading; and employed  
7 devices, schemes and artifices to defraud in connection with the purchase and sale of  
8 securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive  
9 the investing public, including Plaintiff and other Class members, as alleged herein; (ii)  
10 artificially inflate and maintain the market price of Acelyrin securities; and (iii) cause  
11 Plaintiff and other members of the Class to purchase or otherwise acquire Acelyrin  
12 securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and  
13 course of conduct, Defendants, and each of them, took the actions set forth herein.  
14  
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18

19           56. Pursuant to the above plan, scheme, conspiracy and course of conduct, each  
20 of the Defendants participated directly or indirectly in the preparation and/or issuance of  
21 the quarterly and annual reports, SEC filings, press releases and other statements and  
22 documents described above, including statements made to securities analysts and the  
23 media that were designed to influence the market for Acelyrin securities. Such reports,  
24 filings, releases and statements were materially false and misleading in that they failed to  
25  
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28

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

3  
4 57. By virtue of their positions at Acelyrin, Defendants had actual knowledge  
5 of the materially false and misleading statements and material omissions alleged herein  
6 and intended thereby to deceive Plaintiff and the other members of the Class, or, in the  
7 alternative, Defendants acted with reckless disregard for the truth in that they failed or  
8 refused to ascertain and disclose such facts as would reveal the materially false and  
9 misleading nature of the statements made, although such facts were readily available to  
10 Defendants. Said acts and omissions of Defendants were committed willfully or with  
11 reckless disregard for the truth. In addition, each Defendant knew or recklessly  
12 disregarded that material facts were being misrepresented or omitted as described above.

13  
14  
15  
16 58. Information showing that Defendants acted knowingly or with reckless  
17 disregard for the truth is peculiarly within Defendants' knowledge and control. As the  
18 senior managers and/or directors of Acelyrin, the Individual Defendants had knowledge  
19 of the details of Acelyrin's internal affairs.

20  
21  
22 59. The Individual Defendants are liable both directly and indirectly for the  
23 wrongs complained of herein. Because of their positions of control and authority, the  
24 Individual Defendants were able to and did, directly or indirectly, control the content of  
25 the statements of Acelyrin. As officers and/or directors of a publicly-held company, the  
26 Individual Defendants had a duty to disseminate timely, accurate, and truthful information  
27  
28

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

10  
11  
12  
13  
14 60. During the Class Period, Acelyrin securities were traded on an active and  
15 efficient market. Plaintiff and the other members of the Class, relying on the materially  
16 false and misleading statements described herein, which the Defendants made, issued or  
17 caused to be disseminated, or relying upon the integrity of the market, purchased or  
18 otherwise acquired shares of Acelyrin securities at prices artificially inflated by  
19 Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known  
20 the truth, they would not have purchased or otherwise acquired said securities, or would  
21 not have purchased or otherwise acquired them at the inflated prices that were paid. At  
22 the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of  
23 Acelyrin securities was substantially lower than the prices paid by Plaintiff and the other  
24  
25  
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1 members of the Class. The market price of Acelyrin securities declined sharply upon  
2 public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.  
3

4 61. By reason of the conduct alleged herein, Defendants knowingly or recklessly,  
5 directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5  
6 promulgated thereunder.  
7

8 62. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff  
9 and the other members of the Class suffered damages in connection with their respective  
10 purchases, acquisitions and sales of the Company's securities during the Class Period,  
11 upon the disclosure that the Company had been disseminating misrepresented financial  
12 statements to the investing public.  
13  
14

## 15 **COUNT II**

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

17 63. Plaintiff repeats and re-alleges each and every allegation contained in the  
18 foregoing paragraphs as if fully set forth herein.  
19

20 64. During the Class Period, the Individual Defendants participated in the  
21 operation and management of Acelyrin, and conducted and participated, directly and  
22 indirectly, in the conduct of Acelyrin's business affairs. Because of their senior positions,  
23 they knew the adverse non-public information about Acelyrin's misstatement of income  
24 and expenses and false financial statements.  
25  
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28

1           65. As officers and/or directors of a publicly owned company, the Individual  
2 Defendants had a duty to disseminate accurate and truthful information with respect to  
3 Acelyrin’s financial condition and results of operations, and to correct promptly any public  
4 statements issued by Acelyrin which had become materially false or misleading.  
5

6           66. Because of their positions of control and authority as senior officers, the  
7 Individual Defendants were able to, and did, control the contents of the various reports,  
8 press releases and public filings which Acelyrin disseminated in the marketplace during  
9 the Class Period concerning Acelyrin’s results of operations. Throughout the Class  
10 Period, the Individual Defendants exercised their power and authority to cause Acelyrin  
11 to engage in the wrongful acts complained of herein. The Individual Defendants therefore,  
12 were “controlling persons” of Acelyrin within the meaning of Section 20(a) of the  
13 Exchange Act. In this capacity, they participated in the unlawful conduct alleged which  
14 artificially inflated the market price of Acelyrin securities.  
15

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

3  
4 68. By reason of the above conduct, the Individual Defendants are liable pursuant  
5 to Section 20(a) of the Exchange Act for the violations committed by Acelyrin.

6  
7 **PRAYER FOR RELIEF**

8 **WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

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

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

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

17 D. Awarding such other and further relief as this Court may deem just and  
18 proper.  
19

20  
21 **DEMAND FOR TRIAL BY JURY**

22 Plaintiff hereby demands a trial by jury.  
23  
24  
25  
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