# Allena Pharmaceuticals Reports Second Quarter 2021 Financial Results and Recent Corporate Progress

August 10, 2021

- *ALLN-346 well-tolerated in recently completed Phase 1b study; first patients dosed in Phase 2a program for gout and chronic kidney disease; initial data expected in Q4 2021*
- *June KOL webinar highlighted the unmet need in gout and potential for ALLN-346*
- *Updated plan and timing for first interim analysis of Phase 3 URIROX-2 clinical trial of reloxaliase announced in July*
- *Registered direct offering completed in July with gross proceeds of $28.0 million*

NEWTON, Mass., Aug. 10, 2021 (GLOBE NEWSWIRE) -- Allena Pharmaceuticals, Inc. (NASDAQ: ALNA) ("Allena" or the "Company"), a late-stage biopharmaceutical company deploying its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases, today reported financial results for the second quarter ended June 30, 2021 and highlighted recent corporate progress.

"This is an exciting time to advance our first-in-class, novel oral biologic platform," commented Louis Brenner, M.D., President and Chief Executive Officer of Allena. "We have continued to progress our two clinical programs with the goal of addressing therapeutic needs for patients with rare and severe metabolic conditions for which current treatment options are limited. For our reloxaliase program, we recently announced that we expect to conduct the first interim analysis early next year for patients enrolled in URIROX-2 through November of this year. We believe that this will provide meaningful and timely feedback for the conduct and ultimate completion of the adaptive design trial in patients with enteric hyperoxaluria."

Dr. Brenner continued, "In addition, after successfully completing two Phase 1 safety studies, we are focused on advancing ALLN-346 through Phase 2a studies as a potential treatment for patients with gout in the setting of chronic kidney disease. We expect to accelerate the development of ALLN-346, which has the potential to address an unmet need for gout patients as an alternative to currently available agents that are either dose-limited or contraindicated in patients with gout and chronic kidney disease due to safety and tolerability concerns. We look forward to reporting initial data from the Phase 2a program later this year."

**Recent Corporate Developments**

- **Updated Plan and Earlier Timing for First Interim Analysis of the URIROX-2 Phase 3 Trial**

  In July, the Company announced an updated plan and timing related to the first interim analysis of the URIROX-2 Phase 3 trial investigating reloxaliase, a first-in-class, orally administered, non-absorbed enzyme in development for enteric hyperoxaluria. Reloxaliase is being studied in the adaptive-design URIROX-2 trial, the second of two pivotal Phase 3 clinical trials in the reloxaliase program.

  As part of the URIROX-2 adaptive design, the Company had previously planned to conduct the first interim analysis after 130 subjects had been treated for at least six months and had estimated the timing of this analysis to be in the second or third quarter of 2022. Given the adverse impact of the COVID-19 global pandemic on the rate of patient enrollment in this global study, and considering that enrollment in the study began in early 2019, the Company announced that it had modified its plans and now expects to conduct the first interim analysis, which will include all patients who are enrolled in the trial by the end of November 2021 (currently expected to be approximately 80 patients), during the first quarter of 2022.

  The revised interim analysis, which will be conducted by an independent data monitoring committee, will assess whether the study continues to be adequately powered to evaluate efficacy against the primary endpoint, the change in urinary oxalate levels during weeks 1-4 versus baseline, with the planned enrollment of 200 subjects, or whether the study size should be increased. Any adjustment in study size would be designed to ensure that the statistical power of the study remains sufficiently robust. As previously planned, the interim analysis will also include an assessment of futility with respect to the primary endpoint.

- **Initiation of Phase 2a Program for ALLN-346**

  In July, Allena announced that it had completed a Phase 1b multiple ascending dose study of ALLN-346, its first-in-class,

non-absorbed, orally administered enzyme in development for the treatment of hyperuricemia and gout in the setting of advanced chronic kidney disease. The Company also recently initiated dosing for the ALLN-346 201 Trial, the first of two planned, randomized, double-blind, placebo-controlled Phase 2a trials designed to assess initial bioactivity data and additional safety data for ALLN-346. Initial results from the Phase 2a program are expected during the fourth quarter of 2021.

- **KOL Webinar Hosted by Allena Highlighted Unmet Need in Gout and Potential for ALLN-346**

  In June, the Company highlighted the treatment paradigms and also limitations of existing gout therapies in a webinar hosted with key opinion leader (KOL), Robert Terkeltaub, M.D., Professor of Medicine at the University of California San Diego School of Medicine and Section Chief of Rheumatology at the Veterans Administration Medical Center in San Diego (a replay of the webinar can be found here). Managing gout in the setting of advanced chronic kidney disease remains a significant challenge for clinicians because currently available agents are either dose-limited or contraindicated in these patients. There are approximately 500,000 patients with gout and advanced chronic kidney disease in the United States.

- **$28.0 Million Registered Direct Offering Priced At-the-Market under Nasdaq Rules**

  In July, Allena completed a registered direct offering priced at-the-market under Nasdaq rules. Net proceeds to the Company were $25.4 million after deducting placement agent fees and other offering expenses.

**Second Quarter 2021 Financial Results:**

- Research and development expenses increased by $6.3 million to $10.1 million for the second quarter of 2021 compared to the second quarter of 2020. The increase was primarily due to increased costs incurred for the reloxaliase program along with an increase in costs associated with the ALLN-346 program.
- General and administrative expenses increased by $0.8 million to $3.6 million for the second quarter of 2021 compared to the second quarter of 2020. The increase was primarily due to an increase in consulting and professional services costs and insurance costs.
- Net loss increased by $7.0 million to $14.0 million for the second quarter of 2021 compared to the second quarter of 2020, primarily as a result of the factors noted above.
- The cash and cash equivalents balance as of June 30, 2021 was $26.7 million, which includes $1.8 million of net proceeds raised during the second quarter from sales of common stock through an at-the-market equity issuance facility. In addition, the Company raised net proceeds of $25.4 million from the registered direct offering completed in July 2021.

**Year to Date 2021 (Six-Month) Financial Results:**

- Research and development expenses increased by $9.5 million to $18.0 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The increase was primarily due to increased costs incurred for the reloxaliase program along with an increase in costs associated with the ALLN-346 program.
- General and administrative expenses increased by $1.5 million to $7.2 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The increase was primarily due to an increase in consulting and professional services costs and insurance costs.
- Net loss increased by $11.0 million to $25.6 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020, primarily as a result of the factors noted above.

**Allena Pharmaceuticals, Inc**
**Condensed Consolidated Statements of Operations**
**(in thousands, except share and per share data)**
**(unaudited)**

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Operating expenses: | | | | |
| Research and development | $ 10,090 | $ 3,808 | $ 17,942 | $ 8,454 |
| General and administrative | 3,597 | 2,751 | 7,155 | 5,629 |
| Total operating expenses | 13,687 | 6,559 | 25,097 | 14,083 |
| Other income (expense), net | (285) | (417) | (511) | (478) |

| | | | | |
|---|---|---|---|---|
| Net loss | $ (13,972) | $ (6,976) | $ (25,608) | $ (14,561) |
| Net loss per share attributable to common stockholders—basic and diluted | $ (0.24) | $ (0.26) | $ (0.45) | $ (0.56) |
| Weighted-average common shares outstanding—basic and diluted | 57,932,389 | 26,878,962 | 56,484,811 | 25,808,043 |

**Allena Pharmaceuticals, Inc**
**Selected Condensed Consolidated Balance Sheet Data**
**(in thousands)**
**(unaudited)**

| | As of June 30, 2021 | As of December 31, 2020 |
|---|---|---|
| Cash and cash equivalents | $ 26,656 | $ 35,042 |
| Working capital | 20,524 | 31,127 |
| Total assets | 30,285 | 38,931 |
| Loan payable, net of current portion and discount | 9,880 | 9,853 |
| Total stockholders' equity | 12,267 | 22,569 |

**About Allena Pharmaceuticals**

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company leveraging its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases. Allena's lead product candidate, reloxaliase, is currently being evaluated in a pivotal Phase 3 clinical program for the treatment of enteric hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, chronic kidney disease and other serious kidney disorders. Allena is also developing ALLN-346 for the treatment of hyperuricemia in the setting of gout and advanced chronic kidney disease, with a Phase 1 multiple-ascending dose study recently completed and a Phase 2a program recently initiated.

**Forward-Looking Statements**

*This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning the future clinical, regulatory and commercial potential of reloxaliase, statements regarding enrollment and the timing of the planned interim analysis in the URIROX-2 trial, the impact of an earlier initial interim analysis on the size and duration of the URIROX-2 trial, statements regarding Allena's strategy of pursuing a BLA submission for reloxaliase based upon data from its URIROX program using the accelerated approval regulatory pathway, which strategy is predicated on the FDA's agreement with our predictive model supporting a relationship between UOx levels and kidney stone formation rates, statements regarding Allena's development of ALLN-346 including the timing of planned clinical trials and the announcement of topline data for these trials, and statements regarding Allena's financial position and need for capital. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: market and other conditions, the timing for completion of Allena's clinical trials of its product candidates, risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risks associated with Allena's financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Allena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, as well as discussions of potential risks, uncertainties and other important factors in Allena's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.*

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