100 High Street, 28th Floor, Boston, MA, 02110

Position Title: Head of Regulatory
Department: Regulatory

Our vision is a world where science, passion, and compassion create better todays and more tomorrows.

Company Overview:

Astria Therapeutics (Nasdaq listing, ATXS) was formed following the acquisition of Quellis Biosciences, Inc., by Catabasis Pharmaceuticals in January 2021. Astria is focused on developing its lead program STAR-0215, a potent and long-acting monoclonal antibody plasma kallikrein inhibitor, as the potential best-in-class and most patient-friendly prophylactic treatment option for the prevention of attacks in patient affected by hereditary angioedema. Astria will also seek to develop a pipeline in the areas of allergy and immunology with a focus on rare and niche indications through internal discovery efforts and in-licensing.

Concurrent with the acquisition of Quellis, the Company entered into definitive agreements for a private placement with institutional accredited investors to raise approximately $110 million. The financing was led by Perceptive Advisors, with participation from Fairmount Funds Management LLC, RACapital Management, Cormorant Asset Management, Venrock Healthcare Capital Partners, Logos Capital, BoxerCapital, Acorn Bioventures, Commodore Capital, Surveyor Capital, Acuta Capital Partners, Sphera Healthcare, and Serrado Capital LLC. As of June 20, 2021, the Company had cash, cash equivalents, and short-term investments of approximately $140 million. The Company expects that it has sufficient cash to fund its current operating plan through 2023.

Astria is well-poised to continue successfully advancing their current programs — with the STAR-0215 program on track to potentially demonstrate clinical proof of concept of its differentiated profile and long antibody half-life in Phase 1a next year — in addition to growing and developing additional product candidates and partnerships.

STAR-0215:

Astria's lead program, STAR-0215 is currently in preclinical development for the treatment of HAE, a rare genetic disorder characterized by severe, recurrent, unpredictable, painful, and sometimes life-threatening swelling in the face, limbs, abdomen, and airway. Astria is developing STAR-0215 to be a long-acting monoclonal antibody inhibitor of plasma kallikrein, dosed once every 3 months or longer, with the goal of providing the most patient-friendly chronic treatment option for people living with HAE. The company expects to file an Investigational New Drug (IND) application for STAR-0215 in mid-2022 and plans to initiate a Phase 1 clinical trial with initial results anticipated by year end 2022.

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Position Overview:

Astria Therapeutics is seeking a Head, Regulatory Affairs, to be based in Boston, MA. This position will lead the global regulatory submissions as well as preside over the company's overall regulatory leadership to ensure development and execution of regulatory strategies and plans to enable efficient global development of products in the portfolio.

This senior executive will partner closely with the other R&D functions to guide and execute on the strategic direction of the development programs and assure they are designed to meet regulatory approval standards on a global basis, advancing the company's portfolio towards product approval and subsequent commercial success.

The Head, Regulatory Affairs will be a strategic, dynamic, highly collaborative, and successful senior executive who will have significant experience and a successful track record with global regulatory leadership in both development-stage programs and marketed products. This person will utilize this experience to serve as a true R&D business partner, who, as part of the senior management team of Astria Therapeutics, will contribute to the growth of the company by providing their expertise toward driving programs to registration as well providing expert opinion and assessment of external assets of interest to Astria Therapeutics. Additionally, this executive, as the most senior regulatory voice at the company, will lead and build out the regulatory function and support other peer functions within R&D.

The Head, Regulatory Affairs will also advise internal development functions such as Clinical, Medical, Nonclinical and CMC regarding regulatory impact of development decisions. (S)he will work collaboratively with Quality Assurance to ensure quality systems and compliance are maintained. (S)he will support business development activities including assessing partnership/in-licensing/out-licensing opportunities, collaborate with strategic and government partners, and support government affairs/advocacy activities.

Cultural fit of the successful candidate to the company is an extremely important criterion for their success at Astria Therapeutics. Characteristics sought for a good cultural fit include strong curiosity, intelligence, ability to think strategically and independently, ability to negotiate with and influence key stakeholders and decision makers, a "hands on" approach and attention to detail, ability to build excellent working relationships internally and externally, and an entrepreneurial spirit.

Responsibilities:

The Head, Regulatory Affairs will lead, manage and coordinate global regulatory activities for the company's entire portfolio in collaboration with the R&D, Clinical Development, and Commercial teams.

The successful candidate will play a key role in creating, developing and implementing a regulatory strategy for Astria's pipeline projects and manage global regulatory submissions and ensure that pipeline programs are approved in a timely manner with optimal labeling. The Head, Regulatory Affairs will serve as the primary point of contact with the global regulatory agencies with responsibility for all regulatory agency submissions, action items and communications worldwide.

Specific responsibilities include:

- Provide strategic direction to Regulatory Affairs department; lead Regulatory Affairs group, including hiring, mentoring and leading staff.

- Guide and/or lead regulatory agency interactions, including communications and meetings.
- Provide regulatory leadership and support to project/program teams and Senior Management for all aspects of the development program (nonclinical, clinical, CMC, quality, and labeling).
- Effectively communicate requirements and compliance obligations under laws, regulations, and guidance in the US and around the world.
- Direct and negotiate submissions (IND, CTA, NDA, MAA etc..) and approvals with regulatory authorities.
- Strategize, lead, write and/or supervise the development of and submission of documents/dossiers to regulatory agencies to achieve development goals; ensure on-time, high-quality and regulatory–compliant submissions.
- Provide support to regulatory reviews for due diligence initiatives, including opportunity and risk assessment.
- Contribute to the creation of the overall product development strategy and manage the development, monitoring and delivery of regulatory project plans throughout the life cycle.

Qualifications:

The successful candidate will have an Advanced degree in a scientific discipline (M.S. Ph.D., PharmD) preferred, with at least 12 years of relevant regulatory experience with development and approval of multiple products. Knowledge and experience in the rare disease space and additional complex therapeutic areas is preferred, with an emphasis on allergy and/or immunology. S/he should have a track record of successful interaction with the regulatory agencies, as demonstrated by timely submissions and approvals of pharmaceutical/biotech compounds, ideally in rare or niche indications within various disease states.

Specific professional experience and qualifications include:

- Experience supporting both early and late phase development, including development and filing of associated regulatory submissions.
- Experience in a start-up environment with a balance of risk taking and advancing products efficiently.
- Experience managing and collaborating with outside partners/vendors.
- Ability to collaborate effectively with internal and external key stakeholders.
- Ability to review, understand and explain the regulations and guidance documents to guide project teams.
- Proven success in communicating to and negotiating with FDA and global health authorities and managing clinical trial applications in several geographies around the world (for example US, Europe, Latin America, Asia).
- Ability to drive meetings with various stakeholders: (i) senior management, (ii) regulatory agencies (iii) investors, (iv) expert advisors v) collaborators and vi) project teams.
- Ability to comprehend and operate at high levels to address general issues and dig in deep to evaluate and address specific grass root issues
- Passion, self-starter, outcomes-oriented and innovative thinker.
- Outstanding written, oral, organizational, and interpersonal skills are required for this highly collaborative role.
- Strong understanding of the drug development process.
- Stature, experience, technical credibility, strong relationship management and interpersonal skills to quickly gain confidence both with internal stakeholders (CMC, preclinical, statistics, business development, legal, etc.) and externally among regulatory agencies. An individual who can influence

strategic direction of complex global regulatory issues, solicit information, listen well, persuade others, make important decisions and shape outcomes.

- Flexible and dynamic interpersonal approach, entrepreneurial by nature, a collaborative team player who works well with physicians, scientists, managers, peers and staff.
- An individual who demonstrates humility, good judgment and strong analytical skills and adjusts quickly to changes.
- Excellent organizational and project management skills and ability to think strategically.
- Outstanding presentation, written and oral communication skills required. A clear communicator who can influence effectively both internally and externally.
- A person of the highest integrity.
- Ability to comprehend and operate at high levels to address general issues and dig in deep to evaluate and address specific grass root issues
- Passion, self-starter, outcomes-oriented and innovative thinker.