

August 23, 2016

Brent J. Fields  
Secretary  
Securities and Exchange Commission  
100 F Street NE  
Washington, DC 20549-0609

Re: File No. S7-12-16: *Amendments to Smaller Reporting Company Definition*

To whom it may concern:

The undersigned companies represent the future of biotechnology innovation in the United States. Our businesses support job growth and economic development in all 50 states, and our employees are dedicated to the ongoing search for cures and breakthrough treatments that will change the lives of patients around the world.

Right-sized regulations are of paramount importance to the growth of emerging biotech companies like ours. We depend on the public markets for capital, and our investors expect us to dedicate that capital to our research rather than costly compliance burdens that may not be relevant to our businesses. We therefore applaud the SEC for proposing amendments to the smaller reporting company (SRC) definition that would encompass a wider range of emerging business for whom regulatory costs present a significant burden to growth.

The scaled requirements available to SRCs are an important acknowledgement that investors in smaller companies are not always well-served by one-size-fits-all reporting requirements, and that reduced disclosures allow growing businesses to remain laser-focused on their core mission – in our case, developing life-saving drugs. Because Regulation S-K only sets a minimum bar for disclosure, SRCs are always free to exceed that minimum if their investors or the market demand further information. In short – if investors want information, we hasten to provide it. However, our investors are often less interested in the one-size-fits-all disclosures required by the SEC, which can be costly for us to provide. We appreciate the SEC’s proposal to broaden the scope of Regulation S-K’s scaled disclosures (by increasing the public float marker in the SRC definition) because it will allow more companies and their investors to customize certain aspects of their quarterly and annual filings to more accurately represent their businesses.

However, we believe that the SEC missed an opportunity to make parallel reforms to the non-accelerated filer definition and reduce our companies’ regulatory costs under Sarbanes-Oxley (SOX) Section 404(b). In a similar manner to Regulation S-K, Section 404(a) of SOX sets a minimum standard for compliance – companies must maintain internal financial controls. We value these controls, and our management and Audit Committees strive to ensure that investors are protected via the requirements of Section 404(a). SOX Section 404(b), meanwhile, requires a costly external audit of these internal controls. For many growing biotechs, that audit represents over \$1 million in innovation capital diverted from the lab that could be better spent hiring scientists or enrolling patients in clinical trials.

Non-accelerated filers are exempt from Section 404(b), but that definition (as with the SRC definition that the SEC proposes to change) excludes many small businesses whose investors would much prefer that their funds remain focused on science. We believe that the non-accelerated filer public float threshold should be raised to \$250 million to match the proposed SRC definition. This change would end the onerous requirement that growing companies pay for an internal controls audit while preserving the option for companies to seek external attestation if they believe they will suffer a lack of investor interest or confidence in its absence.

There is already clear evidence that the market does not in fact demand a Section 404(b) audit as a prerequisite for investing in emerging, innovative companies. The Jumpstart Our Business Startups (JOBS) Act, which has spurred more than 200 IPOs in the biotech industry alone, provides an optional SOX 404(b) exemption for emerging growth companies (EGCs) – and multiple studies have found that virtually no companies are voluntarily forgoing their exemption.<sup>123</sup> It is clear that the market is not demanding an external audit of internal controls, despite the fact that the EGC definition includes companies with up to \$700 million in public float and up to \$1 billion in revenues – much larger businesses than any the SEC is considering classifying as SRCs or non-accelerated filers.

On the other hand, just 10% of biotechs have elected to take advantage of the JOBS Act provision that allows EGCs to delay compliance with future GAAP standards<sup>4</sup> – a concrete example of market influence serving as a *de facto* compliance mandate in the absence of a legal directive from Congress or the SEC. It is clear that, when appropriate, growing biotechs will voluntarily go above and beyond what is required by law in order to support their business and their investors. But it is equally clear that investors do not always demand such far-reaching disclosure. By reforming the non-accelerated filer definition, the SEC would allow many biotechs to make a SOX 404(b) determination that is appropriate for them. As with the exemptions allowed by the JOBS Act, our decision will be guided by the needs of our investors, who remain dedicated to supporting our groundbreaking science and the patients we serve.

As the SEC considers changing the public float qualifier for non-accelerated filers, we would also encourage it to include a revenue component in both the SRC and non-accelerated filer definitions. Public float is largely a marker of our companies' *future* value – the more promising our science is, the higher our public float is. But relying on public float to determine which companies qualify as SRCs and non-accelerated filers paints an inaccurate picture of many small businesses *in the present*. Revenue, on the other hand, more precisely reveals company size. Furthermore, a revenue test would ensure that pre-revenue companies are not forced to divert investment funds – in the absence of products to sell – from science to compliance.

We appreciate the SEC's attention to these important issues, and we are hopeful that the updated SRC and non-accelerated filer definitions will accurately classify companies and provide

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<sup>1</sup> Ernst & Young. "The JOBS Act: 2015 mid-year update." September 2015. Available at [http://www.ey.com/Publication/vwLUAssets/JOBSAct\\_2015MidYear\\_CC0419\\_16September2015/\\$FILE/JOBSAct\\_2015MidYear\\_CC0419\\_16September2015.pdf](http://www.ey.com/Publication/vwLUAssets/JOBSAct_2015MidYear_CC0419_16September2015/$FILE/JOBSAct_2015MidYear_CC0419_16September2015.pdf).

<sup>2</sup> Latham & Watkins. "The JOBS Act, Two Years Later: An Updated Look at the IPO Landscape." April 2014. Available at <https://www.lw.com/thoughtleadership/lw-jobs-act-ipos-second-year>.

<sup>3</sup> Dambra, Michael, Laura Casares Field, and Matthew T. Gustafson. "The JOBS Act and IPO volume: Evidence that disclosure costs affect the IPO decision." *Journal of Financial Economics* 116.01 (2015): 121-143.

<sup>4</sup> Ibid.

significant regulatory relief to the growing businesses, like ours, that will lead America's 21<sup>st</sup> century economy.

Sincerely,

Acorda Therapeutics, Inc.  
Alnylam Pharmaceuticals, Inc.  
Amicus Therapeutics, Inc.  
Aquinox Pharmaceuticals, Inc.  
Ardelyx, Inc.  
Athersys, Inc.  
aTyr Pharma, Inc.  
bluebird bio, Inc.  
Catalyst Pharmaceuticals, Inc.  
Cerevast Medical, Inc.  
CoLucid Pharmaceuticals, Inc.  
Conatus Pharmaceuticals, Inc.  
ContraVir Pharmaceuticals, Inc.  
CymaBay Therapeutics, Inc.  
Dermira, Inc.  
Editas Medicine, Inc.  
Flex Pharma, Inc.  
GlycoMimetics, Inc.  
Graybug Vision, Inc.  
GTx, Inc.  
Horizon Pharma, Inc.  
Hydra Biosciences, Inc.  
Immune Design Corp.  
ImmunoMolecular Therapeutics, LLC

Intercept Pharmaceuticals, Inc.  
Jounce Therapeutics, Inc.  
MacroGenics, Inc.  
MaxCyte, Inc.  
OncoMed Pharmaceuticals, Inc.  
Opexa Therapeutics, Inc.  
Orexigen Therapeutics, Inc.  
OvaScience, Inc.  
Ovid Therapeutics, Inc.  
Pacira Pharmaceuticals, Inc.  
Pain Therapeutics, Inc.  
Portola Pharmaceuticals, Inc.  
Principia Biopharma, Inc.  
Raptor Pharmaceutical Corp.  
Regulus Therapeutics, Inc.  
Relypsa, Inc.  
Sucampo Pharmaceuticals, Inc.  
Sutro Biopharma, Inc.  
Syros Pharmaceuticals, Inc.  
Trevena, Inc.  
Ultragenyx Pharmaceutical, Inc.  
Vitae Pharmaceuticals, Inc.  
Voyager Therapeutics, Inc.