Written Testimony of

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"Beyond Silicon Valley: Expanding Access to Capital Across America"

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Introduction

Chairman Hill, Ranking Member Waters, and distinguished members of the House Committee on Financial Services, I am honored to appear before you today to discuss capital formation in the United States and the need for reforms that support entrepreneurs, protect investors, and promote innovation. My name is Bill Newell, and I am a Senior Business Advisor with Sutro Biopharma, Inc, a public biotech focused on clinical stage development of cancer therapeutics using protein engineering. I have been at Sutro since January 2009, until recently serving as its CEO, and prior to that I worked at another public biotech. I also serve on the Board of the Biotechnology Innovation Organization and chair BIO's Capital Formation Work Group.

I want to commend the members of this Committee for working on a bipartisan basis to improve access to capital through targeted reforms that protect investors and right size needed regulations. In the last Congress, this Committee advanced a number of measures to achieve that goal, and I hope that in this Congress, we will be able to move that legislation into law.

The Sutro Story

Sutro Biopharma focuses on research & development and manufacturing for next generation cancer medicines, primarily antibody-drug conjugates (ADCs). Our company is 22 years old, founded in 2003 with patent-protected technology licensed from Stanford University. I was employee number 19 and until recently we had over 300 employees. Sutro went public in 2018 and at one point Sutro had a market cap in excess of $1 billion. Like many U.S.-based biotechs, Sutro has seen substantial domestic job creation, with about 40% of our work force in or supporting our US-based cGMP manufacturing facility. We built and operate the world's only manufacturing facility utilizing cell-free protein synthesis technology at scale and producing clinical trial materials for Sutro and our partners.

In many ways, Sutro's corporate journey is a microcosm of the small biotech experience. We were initially financed by private investors, including venture capitalists. We raised Series A through E venture rounds totaling approximately $190 million. We IPO'd in 2018, benefiting from the JOBS Act of 2012 that made it easier for small companies to go public. So far, we have

raised approximately $535 million in public market offerings. In addition, collaborations with larger industry players have been essential to our growth. We have received approximately $1 billion in funding and reimbursements for R&D collaborations and/or licensing of product candidates from large and midsized biopharma companies. In addition, at various points in time, we have borrowed from venture lenders. All told, Sutro has raised almost $1.6 billion in the company's history. That eyebrow-raising figure and our over 20-year company journey is, unfortunately, very typical of the small biotech experience in bringing a product to market.

Also, like many biotechs, we have had our share of failures along the way. Four potential medicines have made it to clinic development stage, but then development was halted by us or our partners as they did not meet criteria for continued advancement. This is not unusual in our industry; only approximately 7.9% of products reaching clinical development stage are ever approved and given these high costs and low success rates, small biotech companies and their investors are particularly sensitive to the U.S. policy environment in which we operate.

In the last few years and even more so recently raising new funding for research and development of new medicines has been more challenging as investors have a more risk-off mentality. Bringing a new medicine to approval is very, very expensive and risky. In this environment many companies in our industry have had to downsize and end programs because of limited capital availability. Unfortunately, Sutro is no exception. Recently, our Board made the difficult decision to restructure the company, reduce headcount and deprioritize our ovarian cancer medicine which was in registration-directed clinical studies. Sutro is continuing its mission to bring new cancer medicines to patients but has taken a five year step back in that mission and is focusing resources on its preclinical development candidates. Today Sutro's market cap is under $100 million.

Ensuring a robust domestic biotechnology industry is rightfully recognized as a critical national security issue. In addition, it is also an economic juggernaut, with high growth potential and high wages across the country. Thus, it is critical that we implement and support policies that encourage our development and reexamine policies that deter investment and delay treatments. Accordingly, the focus of the remainder of my testimony is on the importance of prudent capital formation policies to support entrepreneurship and maintain our competitive advantages in what is becoming a very dynamic and aggressive global marketplace.

Access to Capital

It takes, on average, 10.5 years for a candidate entering Phase I to reach regulatory approval.[1] This figure doesn't take into account the lengthy pre-clinical work that needs to be completed before a company can move to clinical trials. A recent survey by Deloitte reported that for 2022-23, the average R&D cost to progress a new pharmaceutical from discovery to launch is $2.3

[1] Biotechnology Innovation Organization, Pharma Intelligence, Qualitative Life Sciences, Clinical Development Success Rates and Contributing Factors 2011-2020 (Feb. 2021), 3.

billion.[2] During this long development process, a substantial amount of the money spent by an emerging biotech on research and development comes directly from investors. Most biotechs remain pre-revenue through their entire time in the lab and the clinic.

Early-stage innovators do not have the luxury of funding their product development through sales revenue. Instead, the groundbreaking research that leads to a company's first product is funded by a series of financing rounds from angel investors, venture capitalists, pharmaceutical companies, and, eventually, public market investors.

Drug discovery is expensive. Scientists are expensive. Clinical trials are expensive. That's why access to capital is so crucial. We are in a constant race against time, to develop a life saving drug before funding dries out.

I've seen this company life cycle firsthand having been a corporate lawyer, and now having worked at multiple biotechs. Many companies do not survive from one financing round to another. Capital is essential. Luckily, Sutro was able to go public, thanks to the bipartisan work of this very Committee 13 years ago, when the Committee passed the Jumpstart Our Business Startups (JOBS) Act.

The JOBS Act rightsized regulations for smaller and emerging growth companies. We need to build off the success of the JOBS Act and ensure that American innovators have efficient access to broad pools of capital, that all pools of capital are liquid with various exit opportunities, and that reporting standards are updated to reflect current market standards.

Private Markets

Private markets play a crucial role in the growth and success of small biotech firms. These markets provide essential funding for early-stage companies that are pre-revenue. A company often starts with just angel investors.

What can Congress do to help smaller private companies?

Amend the Accredited Investor definition

The Equal Opportunity for All Investors Act, sponsored by Rep. Flood

Angels are the critical first dollars that bridge the 'valley of death' for the biomedical innovation ecosystem. We need more angels, not fewer. Without angel investors, the rate of innovation would significantly slow. The "Equal Opportunity for All Investors Act" expands the pool of angel investors.

The current definition for accredited investor is not based on the assessment of investment risks, how to evaluate opportunities, or how conduct due diligence. Rather, the current standard is

[2] Deloitte, Unleash AI's Potential: Measuring the Return from Pharmaceutical Innovation 14th ed. (April 2024), 6.

entirely predicated on wealth and the ability to absorb total loss. Wealth should not be the sole determinant of investment knowledge, so this bill directs the SEC to create a thorough accredited investor exam that allows more people who understand investing to participate in the marketplace.

Public Markets

We have the deepest, most liquid, and most competitive equity markets in the world. But fewer companies are going public these days for a variety of reasons. It's expensive to be a public company – funds must be diverted away from critical R&D, clinical development, and scientists and more towards regulatory filings, paperwork, quarterly reporting, and accountants and lawyers.

The biotechnology market has seen wild market swings over the last several years. The entire sector saw speculative inflows as the response to COVID attracted public monies even if companies were not developing drugs to directly respond to the pandemic. For instance, many companies like Sutro and other companies working on cancer therapeutics or treatments for rare diseases also saw market fluctuations. The epic market swing forced companies to exit the emerging growth company, or EGC, exemption and forced them to comply with new regulatory filing requirements despite the fact that their stock prices receded shortly after breaching the thresholds.

The public market vacillations caused Sutro and other companies to trigger certain additional reporting requirements. This trigger event was not based on company fundamentals, such as finally having product revenues. It was just a blip in the market that caused more reporting requirements.

<u>What can Congress do to help smaller public companies?</u>

Extend the Emerging Growth Company Definition

The Helping Startups Continue to Grow, sponsored by Rep. Steil

The Emerging Growth Company (EGC) designation is a critical reason why the JOBS Act was so successful at incentivizing IPOs, especially from small companies. EGCs currently must have less than $1.235 billion in annual revenues or less than $700 million in public float to take advantage of the EGC designation. EGC status currently lasts for five years. Most biotechnology companies that make the transition into public markets do not generate revenue for years beyond the current five-year EGC exemption limitation. Sutro is a prime example. The five-year timeline is simply too short for small biotechs. It's like having a tax system based on age, instead of income, which makes no sense.

This bill allows for an additional five-year extension of the EGC exemption, which aligns with economic realities, better serves the original intention of the JOBS Act, and still preserves investor protections.

Updating and aligning the definition of Small Business
The Small Entity Update Act, sponsored by Rep. Wagner

The SEC needs to report on and revise the definition of Small Business. The noncontroversial "Small Entity Update Act" does just that. It passed this Committee 42-0 last Congress and then passed the House 367-8. So we appreciate the strong bipartisan support for this legislation.

I'm a lawyer, so I don't want to disparage the profession, but small entities simply can't afford to hire a bunch of lawyers and accounting and regulatory experts to comply with the same regulations that a large blue-chip stock must comply with. This legislation directs the SEC to assess regulatory costs of compliance for small and growing businesses, ensuring that regulations placed on these businesses are not overly burdensome. The Small Business Advocate at the SEC has been a great success, and a helpful resource at the SEC, but that office has limited power so having the Commission review and revise the definition of Small Business would be very helpful.

Revising Regulatory Thresholds

In addition to the SEC needing to update their small business definition, the SEC needs to also update their public float threshold triggers. Chairman Tim Scott included a provision in his bill, *Empowering Main Street in America Act*, that would require the SEC to revise thresholds for smaller reporting companies to account for a 12-month rolling average of $700 million or less for their public float. By converting public float thresholds from hard triggers to a rolling average trigger, it avoids surprise expenses for companies that may have a small, temporary blip in their stock price.

Conclusion

In conclusion, I support transparent and reliable capital markets, both private and public, that allow companies to efficiently "graduate" or transition across funding structures while minimizing overlap in reporting and disclosure burdens. Disclosures and reporting obligations should be scaled as a company matures and generates revenues.

Small tweaks can mean a big difference for emerging biotechnology entrepreneurs who continue to face a tidal wave of challenges. Congress should build off the successful implementation of the JOBS Act and pass legislation that will enhance capital formation, including the *Equal Opportunity for All Investors Act*, *Helping Startups Continue to Grow Act*, and the *Small Entity Update Act.*

Thank you for inviting me to provide my perspective on these issues. I welcome the Committee's questions.