Written Testimony of

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Introduction

Chair Wagner, Ranking Member Sherman, and distinguished members of the Subcommittee on Capital Markets, thank you for the opportunity to testify today. My name is Frank Watanabe and I am honored to share my perspectives as President and CEO of Arcutis Biotherapeutics, Inc., a public biopharmaceutical company based in California. I am also the Vice Chairman of the Board of Directors of the Biotechnology Innovation Organization (BIO), which represents Arcutis and over 1,200 other growth-stage biotechs that are driving the search for the next generation of cures and breakthrough medicines.

About Arcutis Biotherapeutics, Inc.

Arcutis Biotherapeutics, Inc. is a young biotechnology company dedicated to developing meaningful innovations to solve some of the most persistent challenges facing patients with immune-mediated dermatological diseases. Arcutis was created out of recognition that innovation in the medical dermatology space had atrophied, forcing many patients to rely on outdated and suboptimal treatments. We focus on developing treatments that address the unmet needs of adults and children suffering from serious inflammatory skin diseases such as plaque psoriasis, atopic dermatitis, and seborrheic dermatitis.

Arcutis was founded in 2016, and we raised three rounds of private financing prior to going public in January 2020 on the NASDAQ exchange (ARQT). We received our first FDA approval in July 2022, have since received FDA approval for two additional treatments, and continue to invest in developing our portfolio of innovative drug candidates. Since our founding, we have invested some $1.4 billion in developing our products, having run 34 clinical trials with our drugs, including 9 large, Phase 3 registrational trials.

In the past 9 years, we have grown from 3 employees to 350 staff today, with operations in all 50 states and employees in 39 states. We are proud to have 2 board-certified dermatologists and 7 dermatology clinicians on staff, and our executive team includes leaders who have worked on

more than 50 FDA-approved products. Our headquarters are in Westlake Village, California, we manufacture our products in San Antonio, Texas as well as Mississauga, Canada, and we have an office in Park City, Utah.

I'm pleased to be here today to discuss policy reforms that can help small innovators—like emerging biotech companies—not only survive but thrive as public companies. My testimony will focus on the challenges Arcutis, along with many of our peers in the biotech sector, have faced under the Sarbanes-Oxley Act of 2002, particularly the requirements of Section 404(b). By sharing our company's experience, I hope to contribute to a constructive dialogue between lawmakers and industry, with the goal of ensuring continued support for breakthrough therapies that companies like ours are working to deliver. To be clear, I fully support regulation, but it needs to be smart regulation that has a purpose. And the compliance costs need to take into account a company's size. I believe it is unreasonable and wasteful to impose the same compliance requirements on a 350-person company with less than $200 million in revenue as those for an 80,000-person company with revenues in excess of $60 billion, but that is what the law currently requires.

Unfortunately, I think it is unlikely that the reforms envisioned in the bill attached to this hearing will relieve Arcutis from 404(b) compliance due to our current capitalization and revenues, but it is my hope that our experience may help other, smaller emerging biotechnology companies avoid unnecessary costs forced by Sarbanes-Oxley Section 404(b).

Unique Position of Biotechs and Challenges of Section 404(b) Compliance for Small Innovators

Like the vast majority of biotech companies, Arcutis is not yet profitable. Drug discovery is expensive, as are scientists and clinical trials. Since our inception, Arcutis has invested $1.4 billion in developing our products, and we generated no sales in our first six years of business. In our nine years of operation, we have not generated a single dollar of profit. Every dollar of our investments in developing, manufacturing, and launching our products has been funded by our private and public investors. And this pattern of high investment costs, long lead times, and reliance on investor capital is typical of the biotechnology industry. In fact, it can often take much longer to develop a drug than it did in our case. Accordingly, our industry places a high value on policies that incentivize investment in innovation and prioritize resource efficiency. Access to capital is crucial. Policies that increase the flow of capital to research and development help produce life-changing and life-saving medicine, whereas policies that divert capital to unnecessary and expensive regulatory burdens stunt innovation.

One of the most burdensome policies for today's biotech innovators is Section 404(b) of the Sarbanes-Oxley Act. Section 404(b) requires the establishment of extensive internal controls and procedures for financial reporting, as well as an external auditor's attestation of those internal financial controls. Though the requirement provides little-to-no insight into the health of an emerging biotech company, it is incredibly costly and onerous for small businesses like Arcutis to comply with.

Arcutis first experienced the overwhelming burden of Section 404(b) in 2021. Although we had yet to generate a single dollar of revenue and had only gone public the year prior, we suddenly became subject to Section 404(b) when the market value of our publicly held shares exceeded $700 million on the testing date of June 30th. And we were not an outlier—within the biotech industry, it's common for small companies with minimal staff, straightforward corporate structures, and no profits to rapidly reach such valuations, as investors value the future potential of creating innovative medical breakthroughs. Yet because 404(b) thresholds are based on rigid, one-size-fits-all market capitalization metrics, we were abruptly held to the same compliance standards as large, profitable multinational corporations.

Two years later, we rolled off Section 404(b) as our stock followed the broader biotech market down, and our public float dipped below $700 million. But even though we technically were not subject to Section 404(b) during the 2023 fiscal year, we couldn't scale back our costly compliance systems, knowing that we would likely become subject to the requirements again, which happened in 2024 as our public float exceeded 404(b) thresholds.

To date, we have spent around $11 million on our compliance with Section 404(b) - approximately the cost of running a large Phase 2 clinical trial. And those costs are rising inexorably- for example, last year our auditor fees went up 24%. Not only did our switch from 404(a) to 404(b) roughly double the fees we have to pay our auditors, but as a small firm, we had to bring in outside control and compliance resources that cost us nearly $500,000 per year. These millions of dollars spent on unnecessary compliance was precious capital that could have been spent on developing life-altering drugs.

And the experience of Arcutis is not unique. One study found that in 2019, Section 404(b) compliance cost emerging growth biotechs an average of over $800,000 per year—that's the equivalent of eight additional researchers, or an additional eight to 16 patients in clinical trials.[1] Studies link 404(b) compliance to a direct reduction in innovation that results in fewer patents. Academic studies also find limited benefits, as biotech investors do not significantly value an additional external report on internal controls for smaller companies, and auditor attestation does not predict future material weakness in internal controls.[2] In short, the academic evidence shows that applying Section 404(b) to small biotechs fails to pass a basic cost-benefit analysis. Instead, it needlessly drains critical capital away from potential cures and breakthrough medicines. If I asked every single one of my investors if they would rather pay an outside firm $2 million every year to issue a report on the effectiveness of the company's internal controls OR use that money towards R&D, the answer in favor of R&D would be unanimous.

I understand the reason for the enhanced controls required by the Sarbanes-Oxley act. We all remember the egregious business abuses that led to the passage of this legislation. But the current thresholds for enhanced compliance requirements enshrined in 404(b) are excessive for

[1] Craig Lewis and Joshua White. Science or Compliance: Will Section 404(b) Compliance Impede Innovation by Emerging Growth Companies in the Biotech Industry? (February 2019)
[2] Ibid.

small companies like mine, and Congress and the SEC should take steps to adjust those thresholds so that these onerous requirements do not draw valuable resources away from R&D investments.

Expanding Section 404(b) Exemptions to Protect Small Businesses

The biotech industry is grateful to Congress and the SEC for their previous efforts to reduce Section 404(b) compliance burdens on small businesses. With that being said, there is still more work to be done. It is important for lawmakers to recognize the unique aspects of the biotech industry and consider further expanding exemptions from Section 404(b) compliance for emerging biotech innovators with little or no revenue.

A recent example of prior efforts to ease compliance burdens came in March 2020, when the SEC voted to create a narrow exemption from Section 404(b) for certain smaller reporting companies with a public float of less than $700 million *and* revenue less than $100 million. While this was certainly a step in the right direction, the amendment overlooked emerging businesses with high valuations, a common predicament for up-and-coming biotech companies. More specifically, by using "and" language, rather than "or", the SEC failed to provide relief to small businesses like Arcutis, which had a public float above $700 million, but zero annual revenues when we first became subject to 404(b) in 2021. There are many other small businesses in a similar predicament, where revenue may be low or non-existent, but their valuation is high.

Amending Section 404(b) Exemption for Low-Revenue Companies

Looking ahead, Congress has several opportunities to support small business innovators by reducing the disproportionate burden of Section 404(b). One approach, as contemplated by the bill attached to this hearing, would be to adjust the public float (from $700m to $900m) and revenue thresholds (from $100m to $250m) for SRCs, which is certainly needed. Congress may also want to consider amending the language of the 2020 targeted exemption for low-revenue companies, so that companies that qualify as SRCs *or* report less than $250 million in annual revenue could qualify. These changes would reflect the fact that many companies, particularly in the biotech sector, retain the characteristics of small businesses despite having high market valuations. Updating the exemption in this way would better align Sarbanes-Oxley compliance requirements with the economic realities these companies face.

Implementing "Soft Triggers" for Public Float Thresholds and Revenue Thresholds

Another option would be to implement "soft triggers" rather than "hard triggers" for public float thresholds. Currently, the 404(b) threshold is simply based on whatever our public float number is on the last business day of the most recently completed second fiscal quarter. Under a "soft trigger" for public float, a company might only become subject to Section 404(b) if it consistently exceeds the threshold over a defined averaging period, such as 12 months, rather than based on a single point-in-time measurement as is the case now. This approach would prevent companies that briefly surpass the threshold from being unnecessarily burdened by costly compliance requirements. It would also provide greater stability for small businesses, protecting them from the volatility and uncertainty that arises as stock prices fluctuate around the

threshold. One day of market fluctuation should not trigger an extra $11 million in expenses for our company.

A one-day snapshot of a company's public float may not tell an accurate story, just like one year of annual revenue may not accurately tell a company's story. I applaud the proposal in the bill that is attached to this hearing that implements a 3-year rolling average threshold for revenue, instead of just a glimpse at one year's annual revenue.

Revising Accelerated Filer and Large Accelerated Filer Definitions

An additional approach is to revise the definitions of accelerated and large accelerated filers to better account for low-revenue companies with high valuations, a typical feature of the emerging biotech space. Congress should consider raising the public float thresholds for these categories, as the attached bill proposes. For large accelerated filers, it would make the most sense to raise the public float threshold to $900 million to align with the bill's proposed definition of a smaller reporting company.

Congress might also consider establishing a new tier of filers to more effectively distinguish small, emerging businesses from large, profitable corporations. Such a tiered system would ensure that low-revenue innovators like Arcutis are not subject to the same burdensome compliance requirements as mature, highly profitable multinational companies.

It is also very confusing that today you can be a "smaller reporting company" with the SEC and also be an "accelerated filer". The bill attached to this hearing clarifies that smaller reporting companies cannot be large or accelerated filers, which is helpful.

Updating the Emerging Growth Company (EGC) Designation

Updating the Emerging Growth Company (EGC) designation would also provide tremendous relief to early-stage innovators. Under current law, companies lose EGC status once five years have passed since their IPO or if their public float exceeds $700 million, regardless of profitability. As a result, many biotechs that are still years away from having a product on the market or generating revenue are prematurely stripped of their EGC status, despite still operating like emerging companies. Extending the EGC designation by an additional five years and raising the public float threshold would better account for the long development timelines typical of the biotech sector and offer meaningful relief from Section 404(b)'s costly compliance requirements. I want to thank Representatives Steil (R-WI) and Liccardo (D-CA) for leading the Committee on this effort.

There are a number of legislative possibilities and definition changes that would responsibly broaden the pool of companies exempt from Section 404(b), easing regulatory burdens for small business innovators and allowing them to focus resources on advancing breakthrough medical discoveries.

Institutional Proxy Advisory Services

I recognize that it is not the topic of today's testimony, but I would briefly like to commend the Subcommittee for your recent hearings into the institutional proxy advisory industry. Arcutis, like many other public companies, has struggled with inaccuracies in their recommendations, recommendations against board resolutions based on arbitrary and unrealistic criteria, and other challenges. Measures by Congress to reform this corner of the public equity markets is sorely needed, and the legislation being considered by the Subcommittee would be important steps in that direction.

Conclusion

Congress now has a critical opportunity to support American innovation by modernizing Section 404(b) to reflect today's market realities. Small businesses like Arcutis are critical to the biotechnology innovation ecosystem—delivering cutting-edge research, driving medical breakthroughs that improve and save lives, and supporting the United States' national security. But these companies cannot thrive if precious capital invested in them to support research and development is instead consumed by regulatory requirements that offer little practical benefit. Tailored, commonsense reforms—whether by amending existing exemptions, adopting soft triggers, or revising filer definitions—would ease unnecessary burdens, encourage continued investment, and protect the innovation pipeline that fuels future cures. I urge Congress to act now to ensure that the compliance framework fosters, rather than stifles, the next generation of medical discovery.

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

Frank Watanabe