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Subcommittee on Capital Markets and Government Sponsored Enterprises

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Legislative Proposals to Enhance Capital Formation and Reduce Regulatory Burdens

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Executive Summary

- PTC Therapeutics (PTC) is a growing biotechnology company based in South Plainfield, NJ. The Biotechnology Industry Organization (BIO) represents PTC and more than 1,100 other innovative biotech companies, the vast majority of which are pre-revenue small businesses.
- PTC undertook a successful IPO in June 2013 using key provisions in the Jumpstart Our Business Startups (JOBS) Act. More than 140 biotech companies have gone public as emerging growth companies (EGCs) under the JOBS Act, a dramatic change from the constricted IPO environment prior to the law's enactment.
- A healthy public market is key to funding the search for innovative, next-generation medicines and maintaining the U.S. as a global leader in 21st century industries like biotechnology. BIO supports policies that *increase* the flow of capital to innovative small businesses and *decrease* capital diversions from the lab to unnecessary compliance burdens.
- BIO supports the Small Company Disclosure Simplification Act (H.R. 1965), which would exempt EGCs and certain low-revenue issuers from the costly eXtensible Business Reporting Language (XBRL) reporting requirement while requiring the SEC to study and improve the compliance mechanism. BIO believes that growing companies should not have to bear the costs of XBRL until it has been demonstrated to be cost effective and useful to investors.
- BIO supports the Disclosure Modernization and Simplification Act (H.R. 1525), which would require the SEC to review Regulation S-K in order to reduce the regulatory burden on small issuers and eliminate duplicative, outdated, and unnecessary compliance requirements.
- BIO supports the Small Company Simple Registration Act (H.R. 1723), which would allow smaller reporting companies (SRCs) to use forward incorporation by reference on Form S-1.
- BIO supports the Reforming Access for Investments in Startup Enterprises (RAISE) Act (H.R. 1839), which would enhance the secondary market for Regulation A+ offerings.
- BIO supports the Encouraging Employee Ownership Act (H.R. 1675), which would reduce the disclosure burden on firms that offer stock options to their employees.
- BIO supports the Improving Access to Capital for Emerging Growth Companies Act (H.R. 1659), which would broaden the impact of the JOBS Act's IPO On-Ramp.

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Testimony of Shane Kovacs

Good afternoon Chairman Garrett, Ranking Member Maloney, and Members of the Subcommittee. My name is Shane Kovacs, and I am the Executive Vice President, Chief Financial Officer, and Head of Corporate Development at PTC Therapeutics, Inc. (PTC). PTC is a growing biotechnology company located in South Plainfield, New Jersey. We have 250 employees in New Jersey – nearly double our headcount from when we went public two years ago. Our IPO was fueled by the vital capital formation provisions in the Jumpstart Our Business Startups (JOBS) Act, and I want to thank the Subcommittee for the part it played in enacting that game-changing law. I look forward to talking with you today about how the JOBS Act impacted the capital formation ecosystem for growing biotech companies and what steps Congress can take to build upon its success.

PTC, BIO, and the Impact of Innovation

From the beginning, PTC has been dedicated to the search for and discovery of treatments to address the unmet needs of patients suffering from devastating diseases. The company was founded in 1998 by our current CEO, Dr. Stuart Peltz, who was focused on developing an RNA biology platform to combat ultra-rare genetic diseases. We currently have three late-stage clinical programs, focused on treating Duchenne muscular dystrophy, cystic fibrosis, and spinal muscular atrophy. These rare conditions are extremely debilitating, particularly in children, and patients do not currently have any viable treatment options. Our programs are designed to improve the lives of patients and their families – a mission that our company believes is core to its existence.

PTC's dedication to scientific advancement as a means to save lives and help patients is not unique in the biotech industry. The Biotechnology Industry Organization (BIO), of which PTC is a member and on whose Board our CEO serves, represents over 1,100 companies like PTC that are driving the search for cures and breakthrough medicines. The vast majority of BIO's members are small businesses. These emerging innovators are laser-focused on a targeted handful of product candidates, and have a lean staff comprised mostly of scientists and clinicians working to advance the next generation of medicines. The scientific potential of this work is astounding – modern science has given us the keys to unlock the secrets to curing and treating illnesses like cancer, diabetes, epilepsy, multiple sclerosis, cystic fibrosis, Alzheimer's, and HIV/AIDS. Millions of patients suffer from these debilitating diseases across the country and around the world, and biotech innovators are working hard every day to save and improve their lives.

In addition to the life-changing impact that groundbreaking R&D can have on patients and their families, emerging biotech innovators are also key economic drivers. Small biotechs like PTC support nearly 8 million jobs nationwide. Further, these are high-quality, high-paying jobs – the average biotech salary is over $88,000 annually, and compensation regularly tops $100,000 in the drug development space. PTC's home state of New Jersey has seen the impact that a thriving biotech industry can have on a state's economy. The industry supports over 210,000 jobs in our state, contributing more than $33 billion to New Jersey's GDP. PTC has been the beneficiary of the world-class research institutions around the state, and our employees have gone on to work at the universities, healthcare foundations, pharmaceutical companies, and other emerging biotechs that make the Garden State a hotbed of innovation.

Supporting Biotech Capital Formation

New Jersey has seen the impact that federal policymaking can have on innovative industries like biotechnology. Since the passage of the JOBS Act, 12 New Jersey biotechs have gone public using provisions in the law. Other states have seen a similar effect – over 140 biotechs have gone through with an IPO in the three years since the JOBS Act was enacted. To put that in perspective, the three years prior to the JOBS Act saw fewer than 40 biotech IPOs. Further, the JOBS Act has allowed many companies to go public earlier in their development timeline. The last three years have seen 25 IPOs by biotechs in the earliest stages of research (pre-clinical R&D and Phase I clinical trials), compared to just one pre-clinical or Phase I IPO in the five years before the JOBS Act.

Biotech investment is riskiest at the earlier stages of development – scientists discover thousands of compounds for every one that makes it through the FDA approval process – but early-stage innovation is critical to the health of the biotech industry and to patients waiting for breakthrough treatments and cures. The JOBS Act has allowed younger companies to access public financing, driving capital to early-stage research that holds the potential to lead to the next generation of innovative medicines. It is clear that smart policymaking can have an impact on the capital formation ecosystem for innovative companies, and I am thankful that the Subcommittee is once again taking steps to support the growth of America's small businesses.

The JOBS Act has been so successful in the biotech industry because it represents a perfect balance of capital formation incentives and appropriately tailored regulations. This important law allows enhanced access to investors, increasing the capital potential of a public offering, and then reduces the regulatory burden on emerging growth companies, decreasing the amount of capital diverted from R&D. This one-two punch is critical for biotech innovators and has increased the viability of the public market for growth-stage businesses looking to fund their capital-intensive development programs.

For small biotech companies, there are two main roadblocks to growth – the complexity of advanced science and the high costs of breakthrough research. The science of saving lives is complicated, and policymaking can't make genetic targeting or protein modification any less difficult. On the other hand, policymaking can certainly make it easier to fund the research and clinical trials necessary to discover and develop a life-saving medicine.

It can take more than a decade and cost over $1 billion to bring a single groundbreaking treatment from laboratory bench to hospital bedside. At PTC, our total spend over the course of 17 years is over $800 million and we are *just now* on the precipice of our first FDA-approved product reaching patients in the U.S. To complicate matters even further, the entire biotech development timeline is undertaken without the benefit of product revenue. PTC had never taken in a dollar in product revenue before our Duchenne treatment was approved in Europe last year. Early-stage biotech companies do not have the luxury of using the sale of one product to finance the development of another. Rather, the entire cost of drug development is borne by external investors.

Because these pre-revenue small businesses utilize only investment dollars to fund their work, they place a high value on policies that incentivize investment in innovation and prioritize resource efficiency. Any policy that increases the flow of innovation capital to emerging companies could lead to funding for a new life-saving medicine – while any policy that diverts capital to unnecessary and costly regulatory burdens could lead to the same treatment being left on the laboratory shelf. I applaud the Subcommittee for taking steps to incentivize capital formation by considering legislation that will make it easier to access

innovation capital and preserve that capital by reducing the regulatory burden on biotech small businesses.

H.R. 1525, the Disclosure Modernization and Simplification Act

One bill being considered by the Subcommittee, Chairman Garrett's Disclosure Modernization and Simplification Act (H.R. 1525), provides a valuable way of looking at America's current reporting regime for public companies. This legislation would direct the SEC to review and revise Regulation S-K to reduce the regulatory burden on smaller issuers and to eliminate compliance requirements that are duplicative, overlapping, outdated, or unnecessary. This commonsense directive takes aim at the one-size-fits-all nature of much of the public company reporting regime. By directing the SEC to specifically emphasize a flexible approach that scales or eliminates burdensome disclosures, this bill would slow the damaging diversion of capital from science to compliance that many of these rules represent.

The spirit of this legislation should guide how Congress and the SEC approach *all* regulatory requirements for smaller issuers. Forcing small businesses to file the same reports as multinational corporations represents a significant cost burden that can stymie the growth of an early-stage innovator – without providing additional benefits to investors. The Disclosure Modernization and Simplification Act specifically requires the SEC to ensure that all companies, large and small, continue to provide "all material information" to investors – a standard that BIO strongly supports. For emerging biotechs like PTC, an informed investor is a good one. In fact, the testing-the-waters process created by the JOBS Act has been so successful for the biotech industry because it allows companies a platform to disseminate *more* and *more detailed* information to potential investors. But the information that these investors want and need does not always align with what is required by the SEC. Investors find value in biotech companies by understanding scientific milestones and clinical trial progress – not financial disclosures that simply show a decade-plus of R&D expenses. And yet small, pre-revenue biotechs are often required to file the same reports as revenue-generating, profitable corporate behemoths. Other industries surely face their own unique circumstances, and many small businesses across all sectors of the economy endure the cost burdens of overregulation – yet a blanket one-size-fits-all approach prevails.

H.R. 1965, the Small Company Disclosure Simplification Act

A key example of the pervasive one-size-fits-all approach to public company reporting is the eXtensible Business Reporting Language (XBRL) compliance regime. As it currently stands, the XBRL reporting requirement is the definition of a costly regulatory burden that diverts capital from science to compliance – without a corresponding benefit to the company or its investors.

From a financial standpoint, there are three key data points that biotech investors need to understand: 1.) how much cash the company has on hand, 2.) what the company's cash burn rate is, and 3.) how much time that cash will buy the company until it needs to conduct another offering. Outside of those high-level metrics – none of which are the true focus or purpose of XBRL – investors should spend their time learning as much as they can about the company's science, the diseases it is treating, the patient population, the FDA approval pathway, and a hundred other variables that will *actually* determine the company's ultimate success or failure.

Despite widespread knowledge of what information impacts biotech investment decisions, all public companies – regardless of size – are required to provide their financial statements in

the XBRL interactive data format. XBRL "tags" certain data points in an issuer's filing statement and exports them in a standardized layout. The ostensible goal of XBRL is to make financial data comparable across issuers, but it falls prey to the one-size-fits-all problem that inflicts so many reporting requirements. The data that is supposedly comparable is heavily weighted toward traditional metrics that might be useful to an investor evaluating profitable multinational corporations – but that provide little to no insight into the health of an emerging, pre-revenue biotech. Investors largely realize this shortcoming of XBRL and thus do not utilize XBRL reports to evaluate emerging companies. Yet every single public company faces an identical XBRL compliance requirement.

In addition to failing to provide useful information for investors, XBRL reporting is very costly for resource-constrained small businesses. As its name implies, XBRL is actually its own computing language – one that requires specific expertise outside the bounds of traditional financial or accounting training. Companies need experts in the XBRL language to properly file the appropriate reports, so we must turn to external contractors to complete our XBRL filings. The cost of an external XBRL contractor is significant for an emerging company, reducing the capital available for more vital functions like research and development. At PTC, we spend over $50,000 annually on XBRL compliance. The capital we spend on XBRL fees could go to support our clinical testing, but instead we pay for a report that investors do not want or need.

In addition to the high costs of XBRL, the compliance mechanism also puts time pressure on our team at the end of each fiscal year and quarter. Outsourcing to an XBRL expert requires that the internal team complete the traditional filing statement with enough time to spare for the external contractor to complete the XBRL process before everything is due to the SEC. The timeline for quarterly and annual filings is already condensed for small issuers because of our limited compliance staff, and reducing it by a week or more to give the XBRL consultants time to finalize the filing adds pressure on a company's finance team. Further, the risk of a misstatement (a risk which every small company CFO takes pains to minimize) increases as time is compressed and the number of people working with the data swells. Thus, the traditional filing statement must be perfect and complete (i.e., not in draft form and requiring zero future revisions) *before* it goes to out the door to begin the XBRL process. The time pressure that this puts on a small issuer is significant and burdensome.

The time and cost pressures of XBRL are substantial for an emerging innovator – yet, to reiterate, the resources poured into meeting the reporting requirement do not provide any benefit to small company investors. Before I joined PTC I worked at Credit Suisse for 12 years and I don't recall a single investor or potential partner clamoring for XBRL reports or other similar data. As CFO of PTC, I spend a great deal of time talking my investors through our company story, our regulatory pathway, and our clinical results – but I have never received a question about the data that are included in an XBRL report.

Because the costs of XBRL in its current form far outweigh its benefits, BIO and I strongly support the Small Company Disclosure Simplification Act (H.R. 1965), sponsored by Rep. Robert Hurt. This bill would broaden the IPO On-Ramp created by the JOBS Act by exempting emerging growth companies (EGCs) from the requirement to provide financial statements in the XBRL format. The IPO On-Ramp has been extremely beneficial for PTC and other emerging biotechs, allowing us five years to find our feet on the market and focus on growing our company before the full reporting regime kicks in at the dawn of year six. Adding XBRL to the list of regulatory requirements that small companies have an opportunity to ease into fits the spirit of the JOBS Act and would provide important regulatory relief for growing innovators.

Along with the EGC exemption from XBRL reporting, the Small Company Disclosure Simplification Act would also institute a temporary exemption for low-revenue companies while the SEC studies how to improve the compliance mechanism. I appreciate the need for transparency, and, as I have said, biotechs go to great lengths to keep their investors informed. If XBRL can be reformed to provide transparency without unreasonably burdening small companies, I support that goal. That's why I am encouraged that Rep. Hurt's bill gives the SEC the opportunity to study the existing XBRL regime and provides an opportunity for reform. Moving XBRL away from a one-size-fits-all approach while maintaining data transparency and recognizing the importance of resource efficiency at small companies could be an important step toward improving the regulatory framework for emerging businesses.

I applaud Rep. Hurt for introducing the Small Company Disclosure Simplification Act to give the SEC time to improve XBRL while providing temporary regulatory relief to emerging growth companies and low-revenue small businesses, and I encourage the Subcommittee to support this important legislation.

H.R. 1723, the Small Company Simple Registration Act

I applaud the Subcommittee for considering additional legislation that reconsiders the one-size-fits-all framework of so many rules and regulations that impact small companies. For example, Reps. Ann Wagner and Terri Sewell have introduced the Small Company Simple Registration Act (H.R. 1723), which would allow smaller reporting companies (SRCs) to use forward incorporation by reference on Form S-1. Filing Form S-1 in preparation for an IPO is an extraordinary undertaking – and it is very costly for a pre-revenue business. The inability to use forward incorporation by reference on this extremely complex form means that a small company must file amendments to its S-1 each quarter it is on file waiting to go public in order to update the relevant financial information. Using forward incorporation by reference would eliminate that cost burden for the smallest issuers.

BIO and I believe that the Small Company Simple Registration Act is an important first step toward reforming Form S-1. However, most biotechs do not qualify as SRCs because the high costs of conducting innovative research, as well as the strong valuations for innovative companies, mean that their public float exceeds the $75 million limit in the SRC definition. BIO and I believe that eligibility to use forward incorporation by reference should extend beyond SRCs to include EGCs. Connecting the Small Company Simple Registration Act with the IPO On-Ramp would build on the success of the JOBS Act and further reduce the cost burden for pre-revenue biotechs considering a public offering.

H.R. 1839, the Reforming Access for Investments in Startup Enterprises (RAISE) Act

In addition to the IPO On-Ramp provisions in Title I of the JOBS Act, BIO was also a strong supporter of the Regulation A reforms included in Title IV. BIO believes that the increased Regulation A+ offering limit of $50 million – a significant change from the $5 million limit under the previous Regulation A exemption – will provide a valuable fundraising option for capital-intensive biotech companies. The relative ease of conducting a Regulation A+ offering is extremely important to growing biotechs given their need to efficiently use investment capital, and the increased offering limit will better reflect the reality that groundbreaking research is a costly endeavor.

Rep. Patrick McHenry has introduced legislation, the RAISE Act (H.R. 1839), that I believe will further enhance Regulation A+ by ensuring that the legal framework at the SEC

supports the secondary market for the shares offered and sold in Regulation A+ offerings. Without enhanced liquidity on the secondary market, investors could be hesitant to participate in Regulation A+ offerings – but Rep. McHenry has taken the important step to codify the regulatory framework for the resale of restricted securities, enhancing the capital potential of a Regulation A+ offering and ensuring that Title IV of the JOBS Act will have its intended impact.

H.R. 1675, the Encouraging Employee Ownership Act

I am also pleased that Reps. Randy Hultgren and John Delaney have introduced the Encouraging Employee Ownership Act (H.R. 1675), which would reform SEC Rule 701 to allow a wider pool of companies to effectively compensate their employees. By reducing the disclosure burden on firms that offer stock options to their employees, the bill would support a valuable compensation practice that allows small businesses to hire the most highly skilled workers. BIO and I support an effective disclosure regime that preserves the ability of innovative biotechs to attract talented workers and compensate them competitively without incurring additional compliance burdens.

H.R. 1659, the Improving Access to Capital for Emerging Growth Companies Act

Similarly, the Subcommittee is considering the Improving Access to Capital for Emerging Growth Companies Act (H.R. 1659), introduced by Reps. Stephen Fincher and John Delaney. This bill would make technical changes to the IPO On-Ramp in the JOBS Act to ensure it is working as effectively as possible for a wide range of growing businesses. In particular, BIO and I applaud the provision in H.R. 1659 that would allow EGCs to use confidential filing when considering a follow-on offering. Confidential filing has been a key success point of the JOBS Act, allowing companies to time the market and ensure their IPO is as successful as possible. Confidential filing supported PTC's IPO, and I am encouraged that Reps. Fincher and Delaney are taking steps to enhance follow-on offerings as well.

Additional Capital Markets Enhancements

I am encouraged that the Subcommittee is taking proactive steps to enhance capital formation and reduce regulatory burdens for small businesses. BIO and I welcome efforts to support the search for innovation capital at growing companies, and we hope to work with the Subcommittee to enact certain additional reforms that will bolster the fundraising potential of emerging biotechs.

Sarbanes-Oxley and SEC Rule 12b-2

BIO urges Congress and the SEC to take a discerning look at any and all regulations that govern public company disclosures, with the goal of achieving a commonsense, appropriately tailored regulatory environment. For example, BIO supports adding a revenue component to the non-accelerated filer definition in SEC Rule 12b-2, which governs numerous regulatory requirements – including compliance with Section 404(b) of Sarbanes-Oxley (SOX), from which non-accelerated filers are exempt.

SOX Section 404(b) represents a significant cost burden for a pre-revenue company, costing up to $1 million annually – a large sum that comes directly from investment dollars intended for research yet does not offer much protection to investors. SOX is simply the most costly of a cadre of regulatory burdens that divert capital from the lab but fail to provide value to an emerging company or its investors.

Growing biotechs are uniquely harmed by Rule 12b-2's company classifications because the groupings are based on public float. The high cost of biotech research coupled with strong investor interest in life-saving medical advancements means that growing biotechs often have a high public float despite their simple corporate structure and lack of product revenue. Rule 12b-2's reliance on public float as a marker for size begs the question: what does a pre-revenue biotech company with a public float of $400 million truly have in common with a $400 million widget-maker? The biotech is highly valued because it is working toward a groundbreaking treatment that may, *years from now*, save millions of lives. The widget-maker, on the other hand, is highly valued because it is manufacturing millions of widgets *today*. These two companies have little in common beyond their valuations, yet are bound by the same disclosure regime.

BIO supports adding a revenue component to the non-accelerated filer definition in order to give the SEC more accurate company classifications and reduce the regulatory burden on growing businesses. By defining an issuer with annual product revenues below $100 million as a non-accelerated filer, a reformed Rule 12b-2 with a revenue test would more accurately reflect the nature of small public companies. BIO also believes that the $75 million public float ceiling for non-accelerated filers is outdated and does not reflect today's market – and thus should be increased to $250 million. These important reforms were included in the Rep. Michael Fitzpatrick's Fostering Innovation Act, which was approved by the Financial Services Committee in the 113th Congress.

Many growing biotechs, including PTC, have also felt the pressure of the public float ceiling included in the JOBS Act's IPO On-Ramp. Despite the common portrayal of Title I as a five-year On-Ramp, our five years are not actually guaranteed. If a growing company's public float spikes over $700 million during its first five years on the market – a distinct possibility for a biotech with promising science – it could lose its EGC status and the attendant benefits, including its SOX exemption. This leads to uncertainty and the possibility of an increased cost burden that would divert funds from the lab. Indeed, PTC is currently gearing up for SOX compliance despite the fact that we theoretically still have 3 years left in our IPO On-Ramp. I believe that Congress could strengthen Title I of the JOBS Act by providing certainty for EGCs and guaranteeing the IPO On-Ramp for a full five years.

SEC Office of Small Business Policy

BIO also supports efforts to expand the mission of the SEC Office of Small Business Policy to include an emphasis on capital formation. Currently, the only responsibility of the Office is to hold the annual Government-Business Forum on Small Business Capital Formation. BIO is an annual participant in the Forum, but we believe that the Office has far greater potential than such a singular focus. There are bright minds and hard workers staffing the Office – perhaps, at Congress's direction, they could undertake new efforts, in conjunction with the business community, to incentivize capital formation, create an effective disclosure regime, and support the growth of small public companies.

Public Company Accounting Oversight Board

Similarly, BIO believes that the Public Company Accounting Oversight Board (PCAOB) would benefit from an expanded voice from small businesses in its decision-making process. The Board already benefits from the expertise of the investment community via its Investor Advisory Group; BIO believes that emerging companies similarly have insights to offer, especially given the impact that the PCAOB's regulations have on small businesses. BIO would welcome enhanced dialogue between the business community and the PCAOB –

perhaps via a small business ombudsman – in an effort to ensure that investors' capital is spent effectively.

BIO and I applaud the Subcommittee for recognizing the important intersection of capital formation and commonsense regulation, and we look forward to working with the Subcommittee as it engages on these important issues.

Conclusion

The extraordinary success of the JOBS Act in the biotech industry means that the work of the Subcommittee has taken on increased import for emerging biotech companies. The search for capital in our industry is always ongoing – it does not end at the IPO. As such, I strongly support efforts by Congress and the SEC to enhance the capital formation ecosystem and incentivize funding for the next generation of breakthrough medicines.

In addition to capital *formation*, emerging biotechs like PTC put a high value on capital *efficiency*. Every dollar spent on unnecessary regulatory burdens is an investor dollar diverted from the lab. The decades-long development timeline associated with groundbreaking science means that most small biotechs will still be pre-revenue (and thus dependent entirely on investment capital) when their five-year JOBS Act On-Ramp expires. For many innovators, the dawn of year six on the public market will bring with it a new, costly compliance burden. BIO and I believe that a move away from the existing one-size-fits-all regulatory regime will support the growth of these companies beyond the IPO On-Ramp, incentivizing scientific advancement and sustaining small innovative businesses as they continue their efforts to bring life-saving treatments to patients who desperately need them.

I am thankful that Congress was able to pass the JOBS Act three years ago, which supported PTC's public offering, and I am hopeful that it will be able to enact further legislation – like the bills being considered today – that could support the search for breakthrough treatments at the next generation of emerging growth biotechs. I appreciate your dedication to these vital issues, and I look forward to supporting your work in any way I can.