P. MICHAEL STURLA, CHAIRMAN
414 MAIN CAPITOL BUILDING
P.O. BOX 202096
HARRISBURG, PENNSYLVANIA 17120-2096
(717) 787-3555
FAX: (717) 705-1923

HOUSE DEMOCRATIC POLICY COMMITTEE
WEBSITE: www.pahouse.com/policycommittee
EMAIL: policy@pahouse.net
@PADemPolicy

House of Representatives
COMMONWEALTH OF PENNSYLVANIA

HOUSE DEMOCRATIC POLICY COMMITTEE HEARING

Topic: COVID-19's Impact on Pennsylvania's Innovative Economy

G-50 Irvis Office Building – Harrisburg, PA

September 21, 2020

AGENDA

2:00 p.m. Welcome and Opening Remarks

2:10 p.m. Panel of Companies from Life Sciences Pennsylvania:

- Christopher Molineaux
  President and CEO
  Life Sciences Pennsylvania
- Shawn O'Brien
  CEO
  Genomind
- Jonathan Steckbeck
  Founder and CEO
  Peptilogics

2:40 p.m. *Questions & Answers*

3:00 p.m. Panel of Companies from Ben Franklin Technology Partners:

- Dr. Wei-Shin Lai
  CEO
  AcousticSheep LLC
- Tracey Warren
  Co-Founder and CEO
  Astarte Medical

3:20 p.m. *Questions & Answers*

3:40 p.m. Closing Remarks

Jonathan Steckbeck, PhD — Peptilogics
Testimony, September 21, 2020
COVID-19 Impact on PA Innovative Economy

Good afternoon Chairman Sturla, Chairwoman Daley and members of the House Democratic Policy Committee. I am Jonathan Steckbeck, founder and CEO of Peptilogics. Thank you for the opportunity to participate in today's hearing on the impact of COVID-19 on Pennsylvania's innovation economy.

Peptilogics is a biotechnology company that designs and develops novel therapeutic drugs, focusing on disease areas where patients have few or no effective therapeutic options. It is our mission to bring new and effective therapies to patients with these diseases to improve their quality of life, and ultimately to save lives. Our pipeline is currently focused on novel antibiotics targeting drug-resistant infections that do not respond to approved drugs, and our first Orphan Drug Designated therapeutic is undergoing Phase 1 human safety trials.

Making therapeutic drugs is difficult start-to-finish, even under the best circumstances when everything is going well and there are no external challenges. Product development in our industry involves accounting for, and dealing with, unknown unknowns at every step in the process. Consider what it is that we are doing: we take a molecule that did not previously exist and we put it into the most complex system that we know of — the human body — incidentally, which is a system where we don't even know all the rules, and hope that it does what we want it to do, which is cure the disease, without causing too many or severe unwanted side effects. It's a difficult and risky process under the most well-managed circumstances.

Time and capital are our industry's opposing, yet intertwined, drivers of success and risk, and each can have a strong influence on the movement and momentum of the other. It generally requires between $2–2.6 billion invested to bring a new drug to market, with a typical development timeline taking more than 10 years from discovery to approval and first sale. My company, like many other small to midsize biopharmaceutical firms, looks to compress that timeline and cost by operating more efficiently than what can be achieved by the giants of the industry. That efficiency, however, changes the risk profile in the form of a smaller and less diverse portfolio, which is our product pipeline. Maintaining our relatively narrow focus allows us to, ideally, achieve the desired cost and time savings, but the success of each and every program becomes far more important, and sometimes existential, to the overall health

and success of the company. With less buffering protection, unexpected events can have an outsized impact on the business.

I wanted to provide that background as a framework to discuss the impact of the COVID-19 pandemic, which disrupted an already complicated process, and it did so rapidly and with little warning or time to prepare.

As we all know, figuring out how to limit or maintain safe interpersonal contact to slow the spread of the virus has been challenging to say the least. For our company, and from conversations with industry friends and colleagues in similar positions, this is where COVID-19 has had the most direct impact on our ability to maintain timelines. Despite the unprecedented rapid advancement of clinical trials for COVID-19 therapies and vaccines, clinical trials for other diseases have been severely impacted, and often halted, because clinical trials require direct personal contact between patients and medical staff, often in a hospital setting. This is critical, because clinical trials are the most capital-intensive part of the drug development process, and delays to clinical trials significantly impact both timelines and cash, which as I mentioned, have a clear and direct impact on the overall health and sustainability of a company developing therapeutics.

At Peptilogics, we are performing our ongoing clinical trial in Australia, with healthy volunteers in a dedicated investigational unit that is not part of a hospital system, where we did not have to explicitly worry about how to keep COVID-19 patients separate and isolated from uninfected individuals. Many clinical trials, however, take place with patients in a hospital setting, where isolation and segregation of COVID-19 patients became paramount in helping to mitigate the pandemic.

While we were able to continue enrolling our trial, we still incurred delays as we worked to figure out how to keep everyone, both volunteers and medical staff, safe. We were luckier than most in that we were only impacted for two months while safety protocols were developed and put in place during the early phase of the pandemic when information and knowledge was changing rapidly — other clinical trials have been on hold since the early days of the pandemic, now approaching six months. Recent cost estimates including only successful programs suggest an average total cost of $374 million per drug. While development costs are not evenly distributed across development stages, with later stage trials absorbing most of the cost, $374 million distributed equally over a 10-year development timeline yields an average monthly cost of approximately $3 million. Most companies simply cannot absorb those kinds of costs indefinitely, and some will likely close.

While the speed with which COVID-19 therapies and vaccines are being advanced is welcomed, it is neither common nor representative of typical historical or current drug development programs. We still do not know the full impact of the lost time and money from impacted clinical trials, but with one of the most vibrant and innovative life science ecosystems in world, it's likely that Pennsylvania's companies collectively have lost billions of dollars and years of development time. Some companies, and their therapies, will not recover and will become additional casualties of the pandemic. The most devastating real effect of this, however, is that the patients those drugs were supposed to help will now have fewer treatment options for their disease, further compounding COVID-19's human toll.

Thank you again for your time and consideration.