

## Revolutionizing the injection experience. Ensuring patients Love Life.



[lovelifesciences.com](http://lovelifesciences.com) Overland Park KS

Medical Device   Injection   Patient Care   Patient Safety   Healthcare and Pharmaceuticals

### LEAD INVESTOR



**Joseph V. Forlenza**

After spending over 30 years in the pharmaceutical industry, and several years promoting injection medications it was impressive discovering what Love LifeSciences was developing an alternative in the injectable space. The ability to use a single device (MultiPen) for multiple injections combined with a low pain injection will increase the use for patients and reduce the fear when administering injectable medications. This device has the potential to positively impact the lives of those required to self administer medications on a daily basis.

Invested **\$25,000** this round

## Highlights

- 1 Winners of Digital Sandbox KC 2021 & Kansas Department of Commerce KITE Grant 2021
- 2 Highly qualified team and advisors versed in each step to market including MDs, PhDs, JDs, and MBAs
- 3 Targeting \$229B self-injection devices market
- 4 UniPen a Hybrid Injection device - reducing the patient reported pain-points of injection devices
- 5 MultiPen the World's 1st 'Pill-box organizer' for injections
- 6 Rapid FDA studies timeline
- 6 Rapid FDA studies timeline

## Our Team



**Nick Love** Co-Founder and CEO

Nick has a research background in translational medicinal chemistry & pediatric neurodevelopment, has worked as an analyst & researcher for several biotech companies, and is the founder of Kansas City Biotechnology & Pharmaceutical Initiative.

We have seen the problems patients face when trying to use injectable therapeutics both in our families and in the healthcare setting. We have seen the problems that arise when patients skip or double medication doses and the awful outcomes of stopping a medication altogether. What bothers us most about it, is that this is completely preventable.



**Bradley Hopper** Co-Founder and CTO

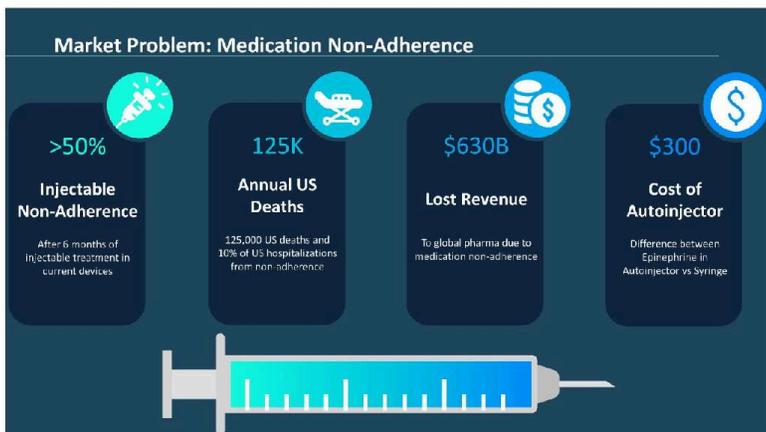
Bradley was the founder of Hopper Design Works at age 20, leading a team in manufacturing custom home furniture pieces before pivoting to rapid device prototyping, development, and 3D printing.



**Cole Huffman** Engineer & Analyst

Cole received his MBA and Engineering degrees at the University of Kansas. He has played a variety of roles in the medical equipment industry including manufacturing, product development, and sales.

## Pitch



Medication non-adherence is one of the world's most pressing healthcare concerns. It is estimated that more than 50% of patients prescribed an injectable

medication stop adhering to those medications just 6-months after starting them - many of these therapies being life saving and life-prolonging.

Medication non-adherence leads to 10% of U.S. hospitalizations, 125,000 annual U.S. patient deaths and costs in excess of \$200B for the U.S. healthcare system.

Non-adherence is not only a problem for the patient and healthcare system, but costs \$630B in lost revenues to global pharma.

Unfortunately, current attempts to solve these problems for injectable medications fall short with some solutions, such as autoinjectors like EpiPen, costing \$300 for patients to have access.



There are currently 3 major techniques medication are generally administered at home. The pre-filled syringe comes preloaded with medication inside and is commonly utilized with most injectable therapeutics. A safety device can be added to a pre-filled syringe to allow for improved needle-stick safety after use, although these devices can force awkward injection angles, are harrowing for patients to look at, and provide little else to support for the patient. Autoinjectors/pens automatically insert a needle and eject medication. With <50% of patients adhering to medications within these devices, Love Lifesciences knew there were problems with each option but we needed to identify what those problems were.



We produced a 392 patient outreach survey with patients administering on average 3.6 injections per week across 37 different injectables. We received a tremendous amount of information including comments stating that autoinjectors are incredibly painful with both how rapidly needles are inserted, causing bruising, and how rapidly medication is ejected, forming a painful bubble under the skin. We found that 36.6% of patients surveyed that have previously used autoinjectors stopped simply because of pain!

After sifting through all of this information, we identified six key points that

After going through all of this information, we identified six key points that would lead to increased injectable adherence: Less pain & anxiety, Easier use, Injection control, No-see needles (40% of the population has a severe needle phobia), Independence/Confidence, and No dosing errors. Thus, we took this information and integrated solutions to each of these points into our devices.



UniPen is a single use injection device which takes a hybrid approach to the injection process, stripping away the patient reported pain-points of autoinjectors and implementing the cost-effectiveness, control, and ease of use that syringes allow.

UniPen functions by allowing patients to manually control the speed of needle insertion and medication ejection, while retaining the major benefits that autoinjectors allow such as no-see needles. Further, UniPen implements pressure ribs at the bottom of the injection site, increasing the pressure around the injection and decreasing pain associated with the needle!

UniPen intellectual property is currently protected by a pending PCT submission, produced through the guidance of Polsinelli Law Firm.

**UniPen – A Hybrid Approach to Injections**

Feature	UniPen	Pre-filled Syringe (PFS)	PFS + Safety Device	Autoinjector
Needle Control	Yes	No	No	No
No-See Needle	Yes	No	No	No
Needlestick Safety	Yes	No	Yes	Yes
Additional Pain Deterrence	Yes	No	No	No
Injection Site Targeting	Yes	No	No	Yes
Medication Ejection Control	Yes	No	Yes	Yes
Preferred Appearance	Yes	No	No	Yes
Low Regulatory Burden	Yes	Yes	Yes	No
Improved Unit Economics	Yes	Yes	Yes	No

In this side-by-side comparison between UniPen, Pre-filled syringes, Safety Devices, and Autoinjectors it is easy to see the major factors that UniPen brings to the table.

2 key points to note that provide an improved device without directly impacting the patient experience are a low regulatory burden and improved unit economics. Both of these benefits come in due to integrating a pre-filled syringe into UniPen during the manufacturing process. We discuss why this is beneficial from a regulatory perspective on the next slide. This is incredibly beneficial to pharma manufacturers when considering unit economics, however. Commonly, when pharma produced an injectable therapeutic they have separate manufacturing lines for their pre-filled syringes and their autoinjectors as both

ot these injection techniques are generally provided. With UniPen, however, a single pre-filled syringe filling line can be extended to allow the addition of UniPen onto the syringe allowing for the ability to use only a single manufacturing line. In doing so, pharma is able to divert some pre-filled syringes to sell independent while allowing the continuation of others to load UniPen devices. This saves pharma a substantial amount of both up-front and per-unit expenses during manufacturing steps.

**UniPen – Regulatory Pathway**



**FDA 510K – Class II Device**

- Consultant – **Biomedical Devices of Kansas**
- Technicality of ‘Syringe Safety Device’ → **Abridged Pathway**
- FDA guidance documents outlining studies
  - **No in-human studies**
  - Must test 500 devices to prove no needle injuries
- ~6-month long process including studies & FDA review

Patent Pending – PCT Submitted

During the manufacturing process, a pre-filled syringe is actually integrated inside of UniPen. By performing this step, Love Lifesciences has created an incredibly abridged FDA pathway for device clearance. This small step allows for the technical designation of UniPen as a “Syringe Safety Device”. Syringe Safety Devices have a much lower regulatory burden relative to autoinjectors as less studies are necessary to prove function. Continually, the FDA has provided guidance documents for Syringe Safety Devices outlining every study required for clearance. The most demanding study? We must test 500 devices on “fruit” to prove no user needle-stick injuries occur. **No in-human studies are required!**

With our FDA 510K consultant at Biomedical Devices of Kansas and an abridged pathway to clearance, UniPen FDA testing and review is estimated to take ~6-months in total.

**MultiPen – Multi-Dose Injection Device**

MultiPen extends on UniPen’s benefits but will be the World’s first “Pill-box organizer” for injection medications.

- Holds up to 7 doses of medication
- Prevents Untimely access to medications
- Prevents Medication error due to forgetfulness
- Can hold multiple *different* medications at once



Patent Pending – PCT Submitted

MultiPen is our multi-dose injection device extending on the benefits of UniPen, but will further be the World’s first “Pill-box organizer” for injection medications. MultiPen can hold anywhere from 2-7 injections at once.

MultiPen prevents untimely access to medications, ensuring patients cannot double-up or skip a dose of medication. By doing so, MultiPen prevents dosing errors as well decreasing the risk of medication adverse events and increasing the likelihood of a therapeutic response for patients. By holding each injection within the same device, patients no longer have to store dozens of autoinjectors in the home.

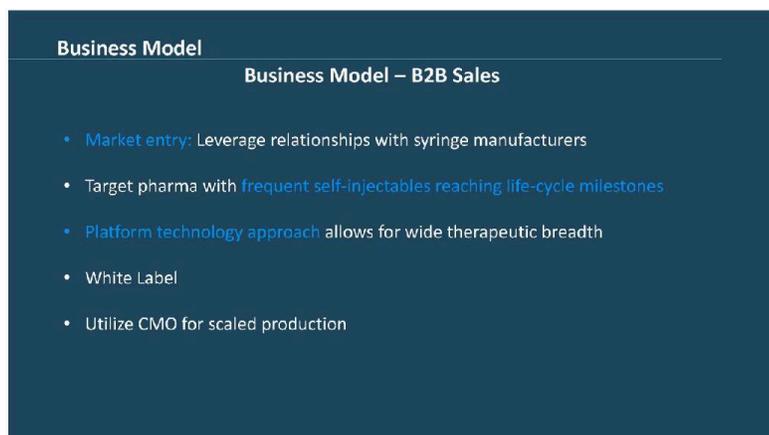
Further, MultiPen can allow for multiple different medications to be store and held at once. This is incredibly beneficial when considering use-cases such as battle-field medicine and intense medication regimens.



Our total addressable market is the injection devices market, projected at \$1.35T by 2028. Our serviceable available market is the self-injection devices market, projected at \$229B by 2027. These markets are growing incredibly rapidly for several reasons:

- 1) The market standard is an injection device - patients will generally selected a device over an open needle syringe.
- 2) Biologics are a relatively new type of therapeutic agent all of which all must be administered through injection. These products generally target chronic disease states. There are currently >300 biologics licensed by the FDA with thousands in the pipeline.
- 3) Across the globe, chronic health conditions are a major concern. In the US alone, 40% of the population or 133M individuals have chronic health conditions with this number rapidly growing annually.

Ultimately, with these 3 factors we see a paradigm shift occurring over the next decade(s) as the increasing number of patients with chronic health conditions have increasing access to injectable therapies for their conditions of which many will be self-administered from home. Love Lifesciences has identified this and is taking action at the very early stages of these rapidly developing markets.



We utilize a business-to-business sales model selling our products to pharmaceutical manufacturers/pharma with frequently administered injectable therapeutics reaching critical life-cycle milestones such as new market entry or generics status. By leveraging current relationships with leading syringe

manufacturers, we look to access their large-pharma partners as a means to enter the market.

Because of UniPen & MultiPen's simplicity of integrating a pre-filled syringe into the device, these products are platform technologies allowing for most injectable therapeutics in a the most commonly used 1mL pre-filled syringe to be implemented. Thus, we have a wide therapeutic application breadth.

By taking a white-label approach we allow pharma to market and brand the devices as their own, allowing them to take advantage of key therapeutic marketing strategies

Finally, by using a contract manufacturing organizations (CMO) for scaled production, Love Lifesciences is able to scale manufacturing of devices quickly without intense up-front costs of vertical integration.

### Projections & Pricing

- Sell unloaded devices to pharma for filling & labeling
- Price Point \$5/UniPen
- MultiPen Target Price Point \$5.25/dose

Revenue Projections (\$5/dose; \$5.25/dose)	2020-23	2024	2025	2026	2027	2028	TOTAL
UniPen New Revenue	-	\$1.96M	\$3.92M	\$3.92M	\$8.80M	\$17.60M	\$35.2M
UniPen Recurring Revenue	-	-	\$1.96M	\$5.88M	\$9.80M	\$18.60M	\$36.2M
MultiPen New Revenue	-	-	-	\$6.06M	\$14.66M	\$29.33M	\$50.1M
MultiPen Recurring Revenue	-	-	-	-	\$6.06M	\$20.73M	\$26.8M
Total Revenue	-	\$1.96M	\$5.88M	\$15.86M	\$39.32M	\$86.24M	\$149.3M
Total Expenses	\$466K	\$814K	\$1.90M	\$4.25M	\$8.40M	\$16.15M	\$32.0M
Total Profit Margin	-\$466K	\$1.15M	\$3.98M	\$11.61M	\$30.92M	\$70.10M	\$117.3M

\*Revenue model justification appended at the end of the deck

\*Forward looking projections cannot be guaranteed.

Love Lifesciences will sell our unloaded device to pharma for filling and labeling for a price point of \$5/UniPen and \$5.25/dose in MultiPen. Once UniPen has been integrated with a select number of therapeutics, MultiPen will be launched in 2026.

Our revenue model explanation (justification) is appended at the end of the slide deck.

### Team & Advisors

#### Team



**Nick Love - CEO**

- Background as Business Analyst & Researcher at Multiple Biotech Companies
- Founder of Kansas City Biotech & Pharma Initiative
- MD/MBA senior at KU



**Bradley Hopper - CTO**

- Founder of Hopper Design Works
- Background in rapid prototyping, design and manufacturing



**Cole Huffman, MBA - Product Engineer**

- Biochemical Engineering Degree; MBA Graduate
- Background in Medical Equipment Manufacturing, Process Development, Sales



**Stefano Bayer - FDA Studies Lead**

- Research Background in Vascular Neuroscience, NIH Funded
- MD/MSCA senior at KU



**Shantu Tussubara - Patient Liaison**

- Founder of Sickie Cell Foundation in Uganda reaching ~100,000 patients
- Master in Biomedical Lab Science, KU, PhD student

Our team is made of individuals that have both been impacted by and have seen the problems with current injection devices. We each have our own areas of expertise including direct patient care, biotech business development, device prototyping, manufacturing, sales, clinical studies, and patient advocacy.

Team & Advisors Advisors



Our advisors bring even more experience to the table with leaders in several key milestones required for Love Lifesciences to successfully develop and market a device. This includes leaders in venture capital, medical leadership, CTOs and CEOs of biotech and device companies with track records of multiple licensed technologies, directors at medical institutes, and even top sales representatives at large pharmaceutical companies. With a team and advisors versed in each milestone necessary to reach market, Love Lifesciences has defined a clear pathway to market.

**Opportunity & Ask**

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## Opportunity

- Targeting \$229B Self-Injection Devices Market
- 2 Initial Products
  - UniPen – Hybrid Injector
  - MultiPen – World’s 1<sup>st</sup> ‘Pill-box organizer’ for injectables
- Ready to initiate UniPen manufacturing & FDA Clearance
- Rapid FDA Clearance – 6-month process
- Highly qualified Team & Advisors versed in each milestone to market

## Ask

### \$200,000

Manufacturing Development  
MultiPen R&D  
IP Coverage

**Revenue Model Justification:**

2024-2025:

- 2/3 Average number of doses sold per therapeutic in mid-frequency injectable therapeutic sub-market “autoimmune injectables” removing outlier blockbuster drugs sales from Humira & Stelara to determine contract size
- 2024 introduces single contract, with 2025 introducing two new contracts
- Contracts are presumed recurring due to the regulatory burden of adjusting an injection device for a therapeutic as well as the burden of rebranding and patient education

2026:

- Introduction of MultiPen
- MultiPen: 1/3 Average number of doses sold per therapeutic in “autoimmune injectables” sub-market removing outlier blockbuster drugs Humira & Stelara
- Presuming integration of MultiPen into previously contracted therapeutic lines
- 2026 introduces two contracts

2027-2028:

- New contracts for UniPen taking 3/10 and MultiPen taking 4/10 Average # of doses sold per therapeutic in high-frequency injectable therapeutic sub-market “Multiple Sclerosis injectables”
- 2027 introduces single contract with 2028 introducing two new contracts

Price point: Compare to autoinjector component purchase cost of \$4 (PA Consulting Group estimates on EpiPen component purchase price), Mylan CEO Heather Bresch statement of EpiPen manufacturing cost at \$34.50

Forward looking projections above cannot be guaranteed.