

## **Investor Presentation.**





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# **Corporate Overview.**

Modular Medical is a development stage medical device company seeking to produce a next generation insulin pump to expand access to a higher standard of glycemic management for people with diabetes.

Founded by Paul DiPerna, **founder of Tandem Diabetes (TNDM)** and original designer of its popular t:slim pump. 30-year veteran of the medical device industry.

Large portfolio of patented technology makes insulin pumps easy to learn, use, and afford.

Addressable Market: \$3 Billion unmet market need MODD1: FDA submission occurred January 19, 2024

Headquarters: San Diego, CA

NASDAQ: MODD





#### Insulin Pumps

Represent the gold standard in glycemic control. Better outcomes, better patient health, lower A1C. (Market share leaders: Medtronic, Tandem, Insulet)

## Out Bette

#### Outcomes

Better outcomes lead to systemic savings: fewer trips to ER, reduced comorbidities. Saves \$10k/patient year (40%) even after cost of pump.

#### Limitations

Feature-heavy and complex systems have hampered adoption. These products are for "superusers." Prohibitive for many to learn and manage.

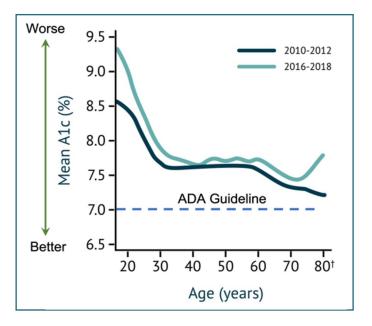


#### **Cost Constraint**

Expense of current offerings has placed them out of reach of many patients and insurance plans. Difficult reimbursement, large out of pocket expense.

# **Current Market.**

- **1 in 4** Healthcare dollars in the US are spent on diabetes and diabetes related complications.
- Only **1 in 3** Americans with type 1 diabetes use a pump. This number has been materially unchanged for 15 years.
- Only 8% of insulin dependent Americans with type 2 diabetes use a pump. This number is just starting to rise.
- Only 21% of T1D's reach ADA guidelines for glycemic control. Overall outcomes have not been getting better.<sup>1</sup>

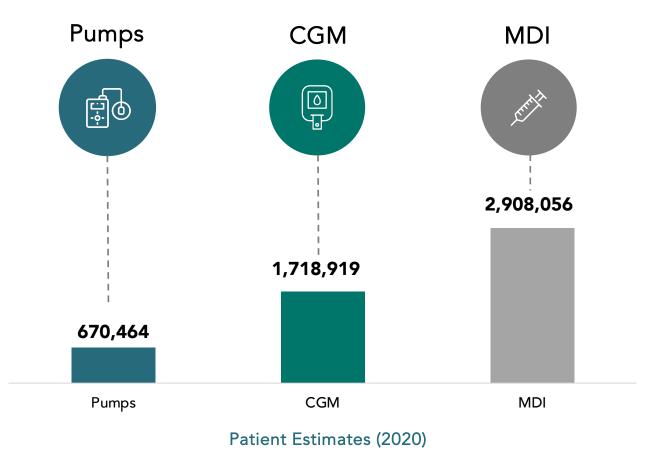


<sup>1.</sup> Meaghan St. Charles et al. Value Health. Jul-Aug 2009

<sup>2.</sup> State of Type 1 Diabetes Management and Outcomes from the T1D Exchange 2016-2018

# US Market Size.

27 million people with diabetes. 3.6 million require daily insulin (1.6M Type 1, 2.0M Type 2).



Only **20%** of insulin dependent people with diabetes use a pump for insulin delivery.

**80%** rely on multiple daily injections (MDI).

Continuous glucose monitors (CGM) have nearly **3X** the user base of pumps.

Patients estimates device type and therapy are for T1D and T2D combined. MDI defined as needing rapid acting and long-acting insulin. Other T2D not included are those on generic orals or diet and exercise only. 2020 National Diabetes Report (CDC). Seagrove Partners LLC, HCP Perspectives August 2021 Precision Xtract September 2018

# Encouraging Adoption.

Abbott Freestyle Libre made continuous glucose monitoring easier and more affordable. This expanded the product category and doubled its size.

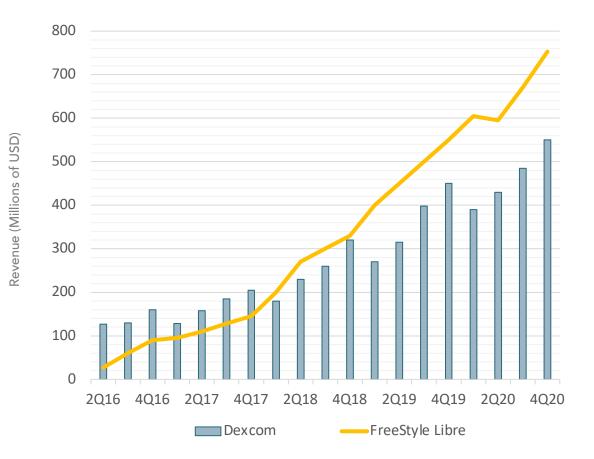
We believe the insulin pump market is ready for a similar transition.

"In short, Flash Glucose Monitoring is fundamentally trying to take something that is more "professional" (i.e., traditional CGM) and make it more accessible to the masses. In consumer-packaged goods, examples of this strategy include home espresso makers (Keurig), cleaning products (e.g., dilatable floor cleaners, spray cleaners, wipes, toilet wands), and teeth whitening (e.g., whitening strips).

In these cases, the new innovation completely changed the entire category; we look forward to seeing if Flash Glucose Monitoring does something similar in diabetes."

#### Kelly Close, 2014

## FreeStyle Libre vs. Dexcom Revenue



# \$3B US market of almost pumpers.

HCPs fairly consistently indicated that about 25% of their MDI population are "almost pumpers", meaning that they have considered going on a pump, understand pump therapy benefits, but want something simpler that doesn't have all the "bells and whistles"...\*

 1.2M
 28% of T1D MDI

 T1D MDI
 28% of T1D MDI

 (\$1.37B)
 28% of T2D MDI

 1.6M
 25% of T2D MDI

 T2D MDI
 25% of T2D MDI

 (\$1.63B)

# What are almost pumpers asking for?

45% expressed a desire to go on pump

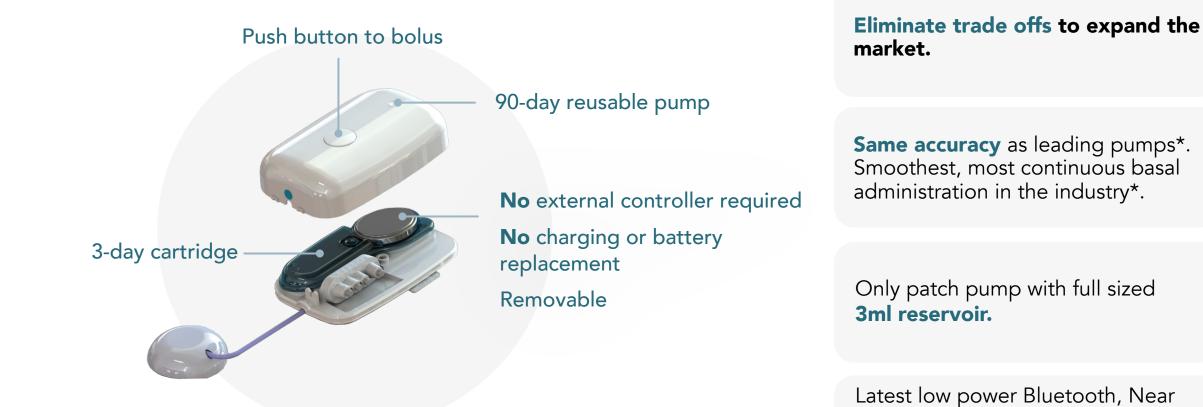
- Make it easy for me
- Make it easy for **my doctor**
- Make it easy to get **coverage**
- Make it easy to share my data with my care team



## **Bottom line:**

*"I cannot spend more time managing my diabetes."* 

# **MODD1** Insulin Delivery for Almost Pumpers.



Currently under research and development, not available for investigational use or sale \*Testing is currently in progress



Field Communications (NFC) and

mobile app for ease of pairing

and data-connectivity.

# **MODD Technology Designed to Provide Precision and Safety.**



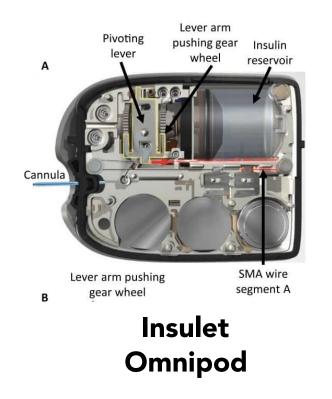


- Precision micro-dosing limits excessive insulin exposure and preserves insulin molecule integrity\*
  - Can be used with the latest ultra rapid insulins\*

- More continuous insulin delivery with small increments as needed, not locked into five-minute intervals like other pumps
- 8 family patents underway to provide a sustainable competitive advantage
- Ultra high-volume major components make low cost manufacturing a reality for the first time in the industry
- **50% lower cost of goods** than leading patch pump

Currently under research and development, not available for investigational use or sale \*Testing is currently in progress

# Simple Design Enables Automated, High-Volume Manufacturing.





# Designed with the Patient & Provider in Mind.

## Provider

- Direct sales Force Focused on Providers
- Free Samples to Encourage Trial
- Point of Prescription Couponing
- Simple to Teach and Support Patients

## Patient

- Only product that you can take home today from doctor's office
- App to Learn Product
- Free 30-Day Trial Coupons
- Co-Pay buydowns
- Reduced outlay of time and money

## Telehealth Optimized

Endocrinologists are perfect candidates for telehealth. They are overworked, underpaid, and need to drive more volume through their practices. Most of what they do can be done online (tests, guidance). There are only 4,000 patient facing endos in the US.

"Remote Patient Monitoring is still a relatively new concept for most respondents, and few knew about the five codes established by CMS However, upon education about the requirement and reimbursement amounts behind these codes, HCPs indicated an overwhelming amount of interest in this mode of patient management, with 85% saying that it was worth their time and effort."

Recently established remote monitoring codes offer \$200-250 reimbursement rate per patient month.

-Seagrove Partners Aug 2021 HCP Perspectives

# Payor Preferred.

Our products are designed to attain preferential reimbursement and avoid the coverage pitfalls many other pumps have experienced.

## **Payor Benefits:**

- 20% Discount vs Insulet (PODD) Provides Preferred Status
- Designed to use PBM codes as a disposable
- No New Code: Reimbursed at Launch
- Saves Provider \$1,032/Patient/Year vs Omnipod

## **National Payor Survey**

Retained ISA to perform National Payors Survey on 1/3 of all commercial lives in US (50 million lives)

Survey data<sup>1</sup> shows that a product with Gen-1 features set at 10-20% discount to Omnipod will gain equivalent or preferential reimbursement at launch.

"I would say that if they could come in with an average monthly cost of, say, 20% less than Omnipod...we would make this our preferred." - IDN

Data shows that discounting and rebates have been uncommon and small in insulin pumps. 5% is currently the largest in the space.

"We expect that the manufacturer will come to the table, probably with an access rebate [of approx. 5%]. This is based on the fact that Medtronic has already come to us with this kind of rebate." - National Health Plan

Payors showed an interest in a simple product that was less expensive.

"I like the simplicity and so as a consequence, it's attractive to me mostly because I'm very price sensitive. I don't think there's any meaningful evidence basis for all those fancy and high-tech products."

- Regional Health Plan

1. Primary research, Precision Xtract, Modular Medical Insulin Pump Rapid-Pulse Payer Assessment, June 2019.



# **Unit Economics.**

Profitable From the First Sale

First month: 1 Re-Usable + 10 Disposables

Price: \$344 Cost: \$34 + \$76.80 = \$110.80 Gross Profit: \$233.20



Subsequent 2 Months: 10 Disposables

Price: \$344 Cost: \$76.80 = \$76.80 Gross Profit: \$267.20



90 Day Re-Usable

Price: FREE Cost: \$34

3 Day Disposable

Price: \$34.4\* Cost: \$7.68

\*Omnipod CPT code with 20% discount

Costs based on internal estimates

# **Business Model.**

New microfluidics technology allows for low-cost pumping of insulin.

**New design philosophy** makes product simple enough for provider driven sales. Enables a classic pharma style business model And a more rapid path to profitability.

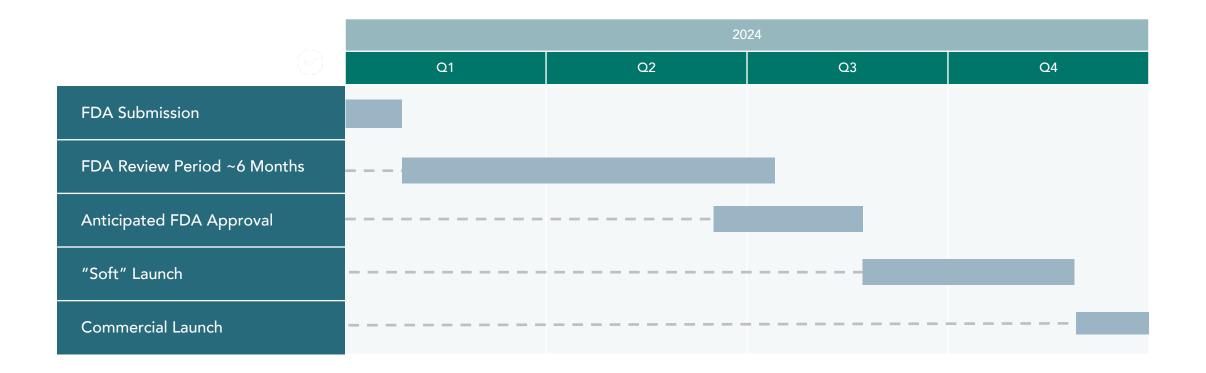


Based on 20% discount to published CPT codes for Omnipod.
 Calculation based on Omnipod US data from SGP 2019 diabetes bluebook and internal cost estimates.

# Timeline.

**Approval:** 510(k) Predicate device approval pathway for FDA label. Same label as Omnipod. Testing is based on benchtop tests, **no human trials required** (no insulin pump has done pre-approval human trials)

Submission: FDA submission occurred January 19, 2024. Anticipated 6-month review period.



# FDA 510(k) Process

Step 1	SubmissionProduct is submitted to the FDA for 510(k) clearance.	Day 0 <b>January 19, 2024</b>
Step 2	Request for ResponseImage: Comparison of the FDA has 60 days from submission to provide a full set of questions for response.	Within 60 Days of Step 1 Received March 15, 2024
Step 3	<b>Response from Modular Medical</b> Modular Medical has 180 days to respond to the requests from the FDA in step 2.	Within 180 Days of Step 2
Step 4	<b>Request for Response #2 or Clearance</b> The FDA has 30 days to respond with a second set of questions or to clear device.	Within 30 Days of Step 3
Step 5	<b>Response from Modular Medical #2</b> Modular Medical has 180 days to respond to the requests from the FDA in step 4.	Within 180 Days of Step 4
Step 6	<b>Interactive Review</b> Question and answers until FDA can clear with the least commercial burden possible.	Interactive
Step 7	<b>510(k) Decision Letter</b> When a decision has been made, the FDA will issue a decision letter.	

In the last two years the average time to 510(k) clearance for an insulin carrying device, excluding COVID and Special 510(k), has been 159 days.







#### MODD1+

(Cell phone controlled adjusted by algorithm)



#### MODD2

(Autonomous, multiple chamber, drug revenue)

# **Product Roadmap.**

MODD1

The Path to the Artificial Pancreas

Currently under research and development, not available for investigational use or sale

# In Development MODD1+.

Enhanced Modular Patch Pump: Cell Phone Controlled



### 2-Factor Authentication

Allows use of user's own cell phone as controller. No dedicated controller required.



## **CGM** Integration

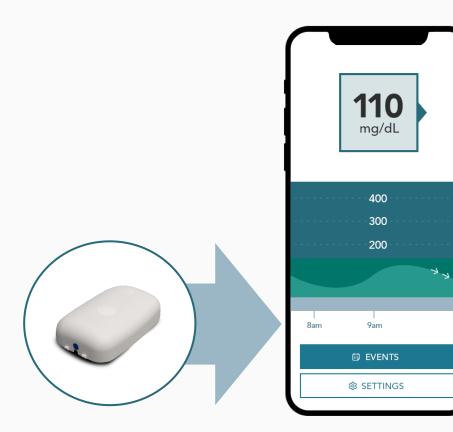
Allows algorithms to adjust basal rate for meals and exercise.



### Ease of Use

Same modular design and ease of use as MODD1, with enhanced control functionality.

## **Cell Phone Controlled**



## In Development

50% complete

# The Future of Care MODD2.

MODD2 is a native multi-chamber pump developed with enhanced ease of use in mind. Designed to be prefilled, the MODD2 will enable Modular Medical to **capture drug revenue**.

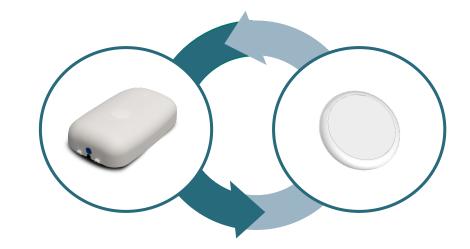
Modular Medical will become the one-stop shop for all of a user's diabetes needs.

## MODD2 Features

- Closed Loop System
- Continuous Glucose Monitor Measures Blood Sugar, Feeds Data to Pump
- Algorithms Inform Pump Activity
- No Human Intervention Required
- Working prototype currently complete

Reuters "US insulin costs" 2012-16, Good RX.
 \$1,088 Avg price for monthly supply from Good RX. Assume ~50% price drop for generic.
 \$4,800 + \$6,000 + \$4,300) X 1.5 million T1 Diabetics = \$22.65bn

## **Artificial Pancreas**



\$4,800

Insulin Spend Patient / Year<sup>1</sup>

# \$6,000

Symlin Spend Patient / Year<sup>2</sup>



Pump System Patient / Year

# \$22.6 B

US Addressable Market<sup>3</sup>



# EU: Single-Payors Want Lower Overall Costs.

Hesitant to Pay Upfront for Durables



## 3 European countries in Top 10 countries for highest number of children and adolescents with T1D<sup>2</sup>

- European single payor systems avoid upfront costs, instead preferring low initial cost and a strong relationship between cost and health outcomes
- Pumps have had limited success in UK and Germany
  - UK guidelines mandate pump usage for all pediatric T1D patients, yet only 1/3 use pumps due to scarce NHS funding. Current funding would buy MODD pumps for all UK pediatric diabetics. \$25-30 million annual opportunity with no direct sales force needed.
  - Low pump penetration outside of Germany and UK. Green-field opportunity



# **Industry Validation**



Manufacturing and design collaboration with Phillips-Medisize, a \$4 billion annual revenue corporation.



Former CEO of Insulet, Duane DeSisto, joined Board of Directors.



Collaboration with Glooko for patient data upload-download. Glooko's platform has been deployed in 8,000 clinical locations in 30 countries.

# **Recent Developments in the Insulin Pump Market.**

Tandem Diabetes purchased AMF's Sigi Patch Pump in December 2022 for 62M CHF (approx. \$69M USD) and 129.6M CHF (approx. 143M USD) in milestones and earnouts

- First pre-clearance purchase of an insulin pump company since 2010 (Roche purchased SNAP!) for \$170M
- Tandem guided on the call to a late 2026 or early 2027 submission

## On May 19<sup>th</sup>, 2023 FDA cleared the Beta-Bionics Pump and I-Let algorithm for management of diabetes

- First new platform pump clearance for full featured electronic pump since the Tandem T-slim.
- indicates regulatory emphasis on ease of use

Medtronic announced the acquisition of EOFlow on May 25th, 2023 for \$738M USD

EOFlow is very similar to a first generation Omnipod that is not approved in the US

# The Team.



## Paul DiPerna

Chairman & CTO

30 years of experience in medical device industry

- Led over 10 projects to FDA approval
- Founder Tandem Diabetes (TNDM:NAS)
- Designer and lead developer of t:slim pump, a leading insulin pump in type 1 diabetes
- Founder and CEO, Modular Medical: an innovative next generation insulin pump

# Proven ability to develop products and win FDA approval

Tandem Diabetes Care – 510k approval on their T-Slim –2012
National Cardiac – 510k approval on a disposable EKG sensor -2018
Ivera Medical – 510k approval on a Luercap for infection control –2015
Baxter Healthcare - FDA approvals (1988-2003) on product in the fields

**Baxter Healthcare** - FDA approvals (1988-2003) on product in the fields of: Blood Canisters, Suction Yankhauers, Wound Drains, High Speed Centrifuges for separating blood, Povidone lodine anti microbials and a variety of blood collection devices.



# James (Jeb) Besser

- 23 year Managing Member, Manchester Management LLC, largest shareholder of Modular Medical, Inc.
- 25+ years of U.S. public equity and capital markets experience, with a focus in life science and technology
- Provided long term strategic planning and due diligence, business development, and investor relations guidance to over 100 public companies
- Active involvement in developing Modular Medical's commercial go to market strategy since 2017

# Capital Structure.

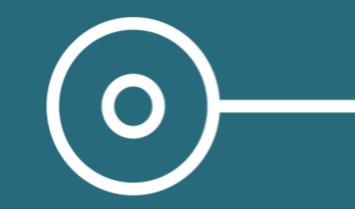
Stock Information				
Listing	NASDAQ			
Symbol	MODD			
Price Per Share – February 22, 2024	\$1.77			
Market Cap – February 22, 2024	\$54.9 M			

Share Structure (at February 22, 2024)				
Shares Outstanding	31.0 M			
Executive & Insider Ownership	21%			
Warrants at \$0.01 Strike Price	1.3 M			
Warrants at \$1.22 - \$1.32 Strike Price	5.1 M			
Warrants at \$6.00 - \$6.60 Strike Price	6.2 M			
Options at \$3.72 WAEP	3.7 M			
RSUs	0.2 M			



### **Investor Relations**

ir@modular-medical.com



NASDAQ:MODD



# Appendix.

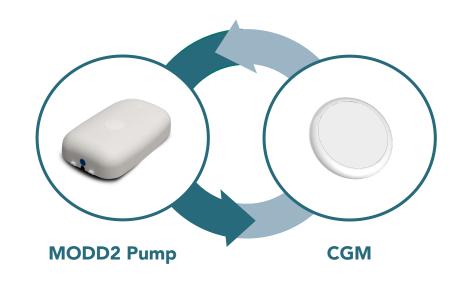
# T1D Insulin Pump Comparisons (US Market).

	Modular Medical	Tandem Diabetes Care	Medtronic (MiniMed)	Insulet
	R			to the order to
Reservoir Size	300 units/3mL	300 units/3mL	300 units/3mL	200 units/2mL
Pump Cost	Pump: \$0 3-Day Disposables: \$349/month (PBM Pricing)	Pump: \$4,200 Disposables: \$134/month	Pump: \$4,600 Disposables: \$148/month	Pump: \$0 Disposables: \$437/month (PBM Pricing)
Monitorable Via Cell Phone	Yes	No	Yes	No
External Controller Required	No	No	No	Yes
Charger/Battery	No Charger/Single-use disposable battery provided	Charger Required	Battery Required	Handset Charging Required
Easy to Learn	Yes	No	No	No
Remove & Reattach	Yes	Yes	Yes	No

# Artificial Pancreas Will Be Multi-Chamber.

- FDA has established 70% Time In Range "no human intervention" standard for AP.
- "Control IQ" study published in NE Journal of medicine barely reached 70% despite announcing meals, sleep, and exercise.
- Prominent KOL's and Algo designers feel 70% TIR without intervention is out of reach with insulin alone: the Artificial Pancreas will have to be multiple liquid.
- Multiple liquid will require small, simple, affordable pumps. Complexity and cost are multiplied. Legacy technology is not well suited.
- MODD well positioned to be first to market with viable multi-chamber product.

## **Artificial Pancreas**



## **MODD2 Features**

- Closed Loop System
- Continuous Glucose Monitor Measures Blood Sugar, Feeds Data to Pump
- Algorithms Inform Pump Activity
- No Human Intervention Required

# MODD Clinical Advisors.

## **ENDOCRINOLOGY**

#### Bruce Bode, MD:

Among the top tier of insulin and insulin pump kols in the world (atlanta, practicing)

#### Orville Kolterman, MD:

Led the development of symlin (pramlintide) and byetta / bydureon (exenatide) at amylin pharmaceuticals (san diego, practicing)

#### Poul Strange, MD:

Led and participated in the development of several insulin products and insulin delivery devices (new jersey, not practicing)

## CDCES, NP, PA

#### Virginia Valentine CDCES:

Recent winner of the outstanding educator of the year from the ADA, author and editor. Board chairperson (new mexico, practicing)

#### Davida Kruger NP:

Former chair at the ADA research foundation, multiple award winner, former editor at numerous publications (detroit, practicing)

#### Gary Scheiner CDCES:

Award winning author of 6 books on diabetes. Founder of integrated diabetes (philadelphia, practicing)

#### Neesha Ramchandani NP:

Focused on technology use, particularly in urban pediatrics (bronx, practicing)

#### Diane Herbert CDCES:

Former VP clinical services at livongo. Published author and frequent speaker (philadelphia, practicing)

#### Chris Sadler PA:

Award-winning previous president of the american society of endocrine pas (san diego, not practicing)

## PHD

#### Lutz Heinemann:

Founder of the profile institute for metabolic research, author of hundreds of publications on diabetes technology, and managing editor of the journal of diabetes science and technology