

**REQUEST FOR INFORMATION NUMBER:270-20240419GLP  
ADDENDUM NUMBER:1**



**REQUEST FOR INFORMATION (RFI) ADDENDUM**

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Issuing Agency:	North Carolina State Health Plan for Teachers and State Employees
RFI Number:	270-20240419GLP
RFI Description:	GLP-1 Solutions
RFI Opening Date and Time:	May 31, 2024, 2:00 PM ET
Addendum Number:	1
Addendum Date:	May 6, 2024
Purchasing Agent:	Kimberly Alston

**FAILURE TO RETURN THIS ENTIRE ADDENDUM MAY SUBJECT YOUR RESPONSE TO REJECTION.**

1. Addendum Number 1 is in response to questions submitted. Responses to questions begin on the next page.
2. Return one signed copy of this Addendum with your RFI response.

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**Execute Addendum Number 1. RFI Number 270-20240419GLP:**

Respondent: OneFul Health Inc.

Authorized Signature:           Edison T. Hudson          

Name and Title (Print): Edison T. Hudson

CEO

Date: May 31, 2024

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Question #	Document Section	Respondent Question	State's Response
1	General	Since [Our Business] and the procedure of endoscopic sleeve gastroplasty (ESG) isn't a GLP-1 or manufacturer, what is your suggestion for us re: the RFI? We believe that ESG would be an excellent option for the NCSHP to consider.	Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan requests that you submit any information, potential solutions, or alternatives relevant to the matter of weight loss benefits/solutions, for the Plan's review and consideration as a response to the RFI.
2	General	What is the timeline for a potential decision? What is the desired go-live date?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.
3	General	Who is North Carolina State Health Plan for Teachers and State Employees pharmacy benefit manager? Is RX carved in or out of the health plan?	The Plan's Pharmacy Benefit Manager (PBM) is CVS Caremark. Pharmacy is carved out from the medical benefit. The Plan's current third-party administrator is Blue Cross Blue Shield of North Carolina.
4	Section 1.0, Page 2	Is there a current vendor providing these services? If so, how may I obtain copies of any incumbent contract documents?	The Plan discontinued coverage for GLP-1s, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss effective April 1, 2024. These benefits were provided through the Plan's PBM Contract. No current vendor provides services that includes these molecular entities as a covered benefit for weight loss. The Plan follows the provisions of the North Carolina Public Records Act for public documents with requests submitted to <a href="mailto:PublicRecords@nctreasurer.com">PublicRecords@nctreasurer.com</a> .
5	Section 2.0, Page 2	Who/what type of physician was prescribing the majority weight loss drugs?	There were no limitations on the type of provider with prescribing authority that can prescribe these medications. That is true for all medications. The requirement is only that the member have a valid prescription and meet the utilization management requirements (if applicable).
6	Section 2.0, Page 2	If this RFI greenlights a solicitation, what is the estimated time frame for procurement?	This is a request for information only, and not a request for services. There is not a set timeline for any decisions. In the Plan's sole discretion, the Plan may take any feasible and financially sound steps to address the fiscal issues of coverage for GLP-1 and GIP-GLP-1 agonists for weight loss, including other potential weight loss alternatives for Plan members.

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7	Section 2.0, Page 2	What is the anticipated contract value?	This is a request for information only, and not a request for services. We do not have an anticipated contract value at this time.
8	Section 2.0, Page 2	<p>What is the number of patients who were taking GLP-1 and GIPs for weight loss in 2023? What is the estimated growth year over year?  Goals for the program for the next 5 years?</p>	<p>There were approximately 24,750 utilizers in calendar year 2023. The estimated growth year over year is 51.2% in 2024; 28.6% in 2025 and 14.8% in 2026.</p> <p>The Plan's goal is to have a solution in place that permits benefit coverage for Plan Members in a financially sustainable manner.</p>
9	Section 2.0 B.1., Page 2	<p>B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:</p> <ol style="list-style-type: none"> <li>1. Pay for varying percentages of the unit cost according to medical necessity considerations.</li> </ol> <p>Can you please elaborate on what this is referring to (i.e., GLP-1)?</p>	Under this cost model, the member's cost share for the medication would vary based on need. For example, a member with a lower BMI and no chronic conditions would have a higher cost share than someone with a BMI of 40 and multiple comorbidities.
10	Section 2.0 B., Page 2	<p>Is there a list of medications that ideally would be included for weight loss?  Will the state consider "off-label" prescriptions i.e., Ozempic for weight loss instead of Wegovy or Moujaro instead of Zepbound?  Is the state open to alternative options such as sterile compounding for these medications while they're on the FDA shortage list?</p>	<p>The specific brand names may expand over time but currently include Saxenda, Wegovy, and Zepbound.</p> <p>The Plan is aware of the possibility for off label use by prescribers and have put specific utilization management guidelines in place to avoid this. The Plan is not interested in off labeled use of a GLP-1, GIP-GLP-1 agonist FDA approved for diabetes (Ozempic, Mounjaro, etc) within our current PBM framework. Consequently, any off labeled use would have to be fully separate from the existing pharmacy benefit administrative processes.</p> <p>The Plan is open to reviewing all legal, feasible, and fiscally sound solutions. Any solution would have to be structured such that it would be administratively feasible.</p>

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11	Section 2.0 C., Page 2	<p>What were the specific parameters for coverage for GLP-1 and GIPs for weight loss before they were removed from the plan?</p> <p>Is there any data from when the meds were covered on efficacy of certain programs or requirements?</p>	<p>The Plan was using the standard utilization management guidelines for the GLP-1 and GIP-GLP-1s for weight loss provided by our PBM (CVS Caremark). This included a prior authorization in line with FDA approved BMI criteria, participation in a comprehensive weight management program for at least 6 months prior to using drug therapy, and quantity limits. Prior to 1/1/2024 this prior authorization permitted attestation from providers and did not require documentation.</p> <p>CVS Caremark updated the standard UM beginning 1/1/2024. This update requires documentation of BMI and comorbid conditions (if applicable). However, the update does not require documentation for participation in a weight management program - CVS permits an attestation. Grandfathered members eligible after 1/1/2024 that had prior authorizations due between 1/1/2024-4/1/2024 were subject to these new guidelines.</p>
12	Section 2.0 C.1., Pages 2 and 3	<p>Would group sessions, virtual coaching or webinar format be allowable for lifestyle coaching options?</p> <p>Will you allow any health coaches who are not certified NBC-HW? (National board-certified health wellness)</p>	<p>Pursuant to RFI Section 3.0 C. 2. "Multiple Responses," the Plan is open to reviewing all alternatives and potential solutions.</p>
13	Section 2.0 C.4., Page 3	<p>Please explain the prohibition on BMI measurements via telehealth. Given the rural nature of North Carolina, in person measurement requirement is likely a very large barrier to care.</p>	<p>The Plan begins within a frame of reference that a provider should meet with the patient to assess BMI and clinical necessity. However, solutions that meet the objective of ensuring an accurate and medically appropriate diagnosis and include components to subsequently ensure correct measurements that maintain accountability for continuation of therapy would be welcomed.</p>
14	Section 2.0 D.1., Page 3	<p>Is a waist to height or waist to hip ratio acceptable in lieu of BMI for program qualification?</p>	<p>The Plan prefers to use BMI for program qualifications if for no other reason than it is used by the FDA for indication, but the Plan would be open to multiple measures that represent alternative thinking.</p>

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15	Section 2.0 D.3., Page 3	Are there any specific qualifications or components required for the weight loss lifestyle management?	There are on specific requirements, but documentation of participation and completion will be required. Attestations will not be sufficient.
16	Section 2.0 E., Page 3	<p>What are the determinants of the program decision in terms of weighted value?</p> <ul style="list-style-type: none"> <li>-Price</li> <li>-Patient experience</li> <li>-Overall value</li> <li>-Small business/Local NC business</li> </ul>	There are no set determinants for making program decisions at this time. The Plan will review all submissions for feasibility and achieving the Plan's fiscal goals solutions.

RESPONSE TO REQUEST TO INFORMATION

North Carolina State Health Plan for Teachers and State Employees

RFI Number: 270-20240419GLP

RESPONSE DATE: MAY 31, 2024

I. OVERVIEW

*OneFul Health Inc. of Cary and RTP North Carolina ("OneFul" or "Company") submit this information, recommendations, and potential solutions to the North Carolina State Health Plan for Teachers and State Employees Plan (the 'Plan') for consideration. These responses include a budgetary estimate to supply the market-leading, lab-certified forms of FDA-approved GLP-1 and GIP/GLP-1 active pharmaceutical ingredients ('APIs') at price points less than twenty percent (20%) of the reported best pricing currently paid by the Plan. A flexible pricing solution with individualized condition agnostic, flexible co-pays is discussed to adapt per the Plan's determined budgetary design. An existing web-based 'soft-PBM' administration system designed explicitly for weight-loss programs products using GLP-1 interventions is recommended for consideration to ensure compliance with online patient screening, pre-approval protocols, and medical guidelines is described. Additionally, we propose to qualify a network of NC-based brick-and-mortar partners to augment member approval, compliance, coaching, and medical follow-up in person. Lastly, the Company is developing a non-drug step-up/step-down complementary medical food product developed by OneFul and several small RTP-based businesses, which the N.C. Biotech Center has been partially funded is described to meet known needs. This product concept has been shown in several clinical trials to increase GLP-1 and PYY satiety peptides materially and presented as the near-future roadmap innovation to enable effective and economical weight-loss maintenance and Type-2 Diabetes treatment augmentation for large patient populations.*

**Submitted by:**

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## II. BACKGROUND

OneFul Health Inc. is committed to developing and producing affordable and highly effective treatments for cardio-metabolic health for over ten years. We invented and patented systems to affordably address the most significant personal and public healthcare costs and the greatest cause of death globally. We personalized generic and approved drugs to match individual patient needs and metabolism. With novel regulatory strategies, current Good Manufacturing Practices (cGMP), and automation, OneFul ensures traceable quality. Our product strategy is to bring highly effective therapies scaled to mass markets at price points typically a fifth of treating chronic diseases.

We are participating in the GLP-1 agonist revolution directly by investing in the lab-certified bulk inventory of the FDA-approved form of semaglutide and tirzepatide, the active ingredient of popular drugs Ozempic/Wegovy and Mounjara/Zepbound. We are making personalized and affordable forms of these GLP-1 and GIP-GLP-1 injectable pharmaceuticals in our wholly owned accredited sterile pharmaceutical facility in Cary, NC, [Triangle Compounding Pharmacy](#), ('TCP'). TCP was the first in North Carolina and one of the earliest nationally to implement a 503B Human Drug Outsourcing Facility and is an approved vendor to UNC Healthcare, Duke Medical, Veterans Administration, and over 7,000 individuals and physicians in nine Southeastern states. The National Pharmacy Compounding Accreditation Board and the North Carolina Board of Pharmacy annually inspect and accredit our sterile and non-sterile facilities.

OneFul is also developing innovative oral therapies to complement GLP-1 agonist injections and serve as pre-hab or step-down aids to metabolic health. We are advised on this development by former leading metabolic drug developers at Glaxo-Smith Kline, distinguished endocrinologists at UNC, and pharmaceuticals experts at the Eshelman School of Pharmacy. In November 2023, OneFul completed the buy-back of Panaceutics.com's assets, a personalized nutrition and clinical foods supplier. Panaceutics made branded products for Abbott Nutrition, Bayer Consumer Health, Microbiome Labs (a Novo-Nordisk company), and niche direct-to-consumer nutraceutical companies. This platform, designed initially by OneFul inventors, creates individualized and prescribed snack-sized (50-gram) squeeze pouches to deliver high levels of ingredients to specific locations in the digestive tract in a single dose. Multiple clinical and animal trials have shown that our GLP-OneFul formulation stimulates native GLP-1 and PYY satiety hormones at levels similar to gastric bypass surgery. The attached whitepaper describes this development.

Founded and operated by native-born North Carolinians, OneFul Health innovates patient-centric healthcare platforms using state-of-the-art robotic additive manufacturing processes. Edison Hudson, CEO and Founder, was a Morehead Scholar at UNC-Chapel Hill, MBA from Duke Fuqua School of Business, and studied robotics and machine intelligence at Oxford University in the U.K. Danny Barnes, PharmD BCSCP Rph, is an N.C. State University biologist who received his PhamD from Campbell University and has served as a regulatory expert at the national level. Our Board of advisors includes pharmaceutical industry veterans and academic experts, including distinguished physicians with decades of medical experience. OneFul's team and its partners are ready to provide our expertise and engage with the Plan's team in an open collaboration to create medically efficacious and economically sustainable solutions.

### III. RFI SPECIFIC RESPONSES

In accordance with the Plan's RFI Number: 270-20240419GLP, to the topics enumerated (in red) our responses are presented (in black):

A. Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss.

- i. GLP-1 agonist peptide mimics as semaglutide, conforming to the FDA-specified base active pharmaceutical ingredient ('API') and chemical form, and is certified by an approved and certified analytical laboratory and supplied to individual patients based on prescriptions typically received by the SureScripts e-prescriptions system. Bulk semaglutide inventory is securely kept in refrigerated storage at TCP in Cary, NC., processed and repackaged under ISO 5 cleanrooms into industry standard 1 ml vials, and provided to patients and practitioners for injection delivered in approved insulin class syringes.
- ii. GIP/GLP-1 agonist peptide mimics, as tirzepatide, conforming to the FDA-specified base active pharmaceutical ingredient ('API') and chemical form is certified by an approved and certified analytical laboratory and supplied to individual patients based on prescriptions typically received by the SureScripts e-prescriptions system. Bulk tirzepatide inventory is securely kept in refrigerated storage at TCP in Cary, NC., processed and repackaged under ISO 5 cleanrooms into industry standard 1 ml vials and provided to patients and practitioners for injection using approved insulin class syringes. Sterility, endotoxin, and particulate matter tests are performed by an independent certified analytical lab at the batch level, typically around 250 doses. Prescriptions are typically delivered or picked up at approved locations.
- iii. The above chemical forms contain the equivalent active peptide ingredients of the brand names Ozempic/Wegovy, Mounjara/ Zepbound. The Saxenda equivalent bulk ingredient is available but is not in inventory at TCP and has not been processed or dispense at this time. The lab testing, processing and dispensing systems used for semaglutide and tirzepatide are thought to be very similar for Saxenda.
- iv. The above peptides are also dispensed for obesity to promote weight loss, as well as conditions of Type 2 Diabetes and relevant cardiovascular conditions, as may be prescribed by licensed physicians at approved and non-standard dosages.

B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:

1. Pay for varying percentages of the unit cost according to medical necessity considerations.



- i. OneFul/TCP can propose a pricing scheme that varies according to medical necessity and physician's dosing recommendations. As a re-packager purchasing bulk APIs, we have complete knowledge and systems to track the materials, labor, testing, and administrative costs associated with filling each specific prescription.
- ii. The cost of the bulk APIs comprise a significant portion of material cost-of-goods ('CoGs') and varies proportional to the prescribed dose of the API.
- iii. For weight loss prescriptions, as per Wegovy standard dosing protocols, the starter dosage of 0.25 mg of semaglutide API constitutes about 30% of the CoGs, whereas the maximum dosage of 2.4 mg of semaglutide API is about 75% of the CoGs.
- iv. For weight loss prescriptions, as per ZepBound's standard dosing protocols, the starter dosage of 2.5 mg of tirzepatide API constitutes about 65% of the CoGs, while the maximum dosage of 15 mg of tirzepatide API is about 87% of the CoGs.
- v. A significant cost of the commercially branded weight loss GLP-1 and GIP-GLP-1 medications is the FDA-approved precision auto-injector variably dosable device. This device's inadequate availability is also a reported cause of the current shortage and the lack of fill capacity for this specialized device.
- vi. OneFul/TCP uses a low-cost, while considered less convenient and user-friendly by some users than the subcutaneous auto-injector devices, the low-cost vial-syringe supplied by TCP is plentifully available and has been a patient self-use device for decades to deliver insulin at home. This approach also allows for non-standard dosing prescriptions, sometimes deemed medically necessary, to reduce adverse side effects in some patients.
- vii. API supply chain issues currently favor the sources curated by OneFul/TCP. We are presently seeing accelerating price reductions for some of these APIs and a noted price elasticity driven by the volume of our bulk purchases. In general, we are witnessing bulk API price reductions of as much as 25%, driven by the increased size of purchases. OneFul/TCP is open to pricing that reflects the impact of larger order quantities that would increase our purchasing leverage from a contract with the Plan.
- viii. The enormous investments by Novo Nordisk, Eli Lilly, and several others in peptide and fill capacity will likely result in market pricing competition. It may also present an issue for our business model if and when the FDA declares that a shortage condition no longer exists for these approved commercial drugs. OneFul/TCP has developed regulatory strategies and product plans that we can implement in less than twelve months to mitigate a change in shortage status and ensure the continuity of our ability to supply API to address weight loss and other indications. OneFul/TCP will share these strategies as part of a definitive procurement contract's warranties.

2. Receive the same effective net price if the Plan only chooses to pay for a medication for an additional FDA indication without paying for it for all other indications.

- i. OneFul/TCP proposes "dosage-driven pricing" based on CoGs and cost to profitably dispense at a level to ensure that our facilities and staff fully meet all FDA and N.C. Board of Pharmacy regulatory requirements. Our pricing proposal will be agnostic to the indication to

which it may be prescribed. Our professional PharmD staff and Quality Assurance shall reserve the right to review any prescription as per our standard operating procedure as regards the safety and any known interactions for a given individual patient and to reject any non-compliant formulations or orders.

- ii. OneFul/TCP acknowledges that the response to this RFI is understood not to be a response to a formal bid requested by the Plan. Further, OneFul/TCP is not committed to achieving specific pricing levels. However, we offer these achievable estimated pricing for standard dosing levels, which is achievable given today's market conditions and our business model:
- iii. Dose Driven Pricing – Condition Agnostic example:

<b>Conditions Indicated</b>		
<b><u>T2 Diabetes</u></b>		
<i>Ozempic Guidelines</i>		
	Dose (mg)	Monthly Script Price*
Initial dose:	0.25	\$ 105.00
Maintenance dose	0.50	\$ 115.00
High dose:	1.00	\$ 140.00
Maximum dose:	1.25	\$ 150.00
<i>Wegovy Guidelines</i>		
<b><u>Obesity</u></b>	Dose (mg)	Monthly Script Price*
Initial dose:	0.25	\$ 105.00
Maintenance dose	1.25	\$ 151.23
High dose:	2.40	\$ 206.47
Maximum dose:	2.40	\$ 206.47
<i>Mounjaro/ Zepbound Guidelines</i>		
<b><u>Obesity/TD Diabetes</u></b>	Dose (mg)	Monthly Script Price*
Initial dose:	2.50	\$ 110.00
Maintenance dose	5.00	\$ 150.00
High dose:	10.00	\$ 275.00
Maximum dose:	15.00	\$ 400.00
*Subject to definitive procurement contract, volume, services, and administrative fees dependent		

- iv. OneFul/TCP has close relationships with other 503A Sterile and 503B Outsourcing Facilities and would agree to enter into contracts to supply these APIs in the same form and under the same quality procedures and on similar terms as a backup to our own TCP facility in Cary, NC.

**3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.**

- i. This disclosure acknowledges that OneFul/TCP does not have adequate administrative capabilities to fulfill this requirement within our small business enterprise. We use internal I.T. and web-based services and systems to receive, validate, process, and track prescriptions. While these systems provide the necessary infrastructure, our systems are inadequate to facilitate the tasks of administering members' claims, rebates, prior authorizations, and compliance.

ii. We have extensive knowledge of partners interested in subcontracting to OneFul or directly to the Plan to fulfill these administrative member compliance requirements.

iii. We have researched available systems for these purposes, which are, in effect, forms of cloud-based "software pharmacy benefit management" ("Soft-PBM"). These systems can interface with our systems through the [Surescript e-prescribing system](#) to meet HIPPA compliance and provider validation.

iv. OneFul recommends that the Plan consider a Soft-PBM explicitly designed to manage the unique acceptance and compliance issues associated with successful programs in weight loss. The attached whitepaper, "The History and Current Burden of Medically Managed Weight Loss", justifies this recommendation.

v. Our top recommendation for such a system to meet the Plan's administrative requirements is [DigbiHealth Inc.](#) ( <https://digbihealth.com/pages/partner> ). The co-founder of Digbi Health is a North Carolina native with extensive knowledge of the administrative challenges for effective weight-loss programs. If desired, we are discussing with him to fulfill a consulting role to work with OneFul and the Plan.

vi. OneFul is developing a complementary GLP-OneFul product line of personalized step-up medical foods to mitigate side effects and as a safety net to prevent catastrophic re-gaining of weight once injection-based treatment ends. This product is being developed to re-stimulate endogenous GLP-1 and other satiety hormones. This article discusses the targeted market and needs:

["Ozempic Patients Need an Off-Ramp"](#)

(<https://www.msn.com/en-us/health/other/ozempic-patients-need-an-off-ramp/ar-BB1mRgHB?ocid=msedgntp&pc=U531&cvid=1795492d68c0488ed335d9654b0e59e4&ei=49>)

vii. OneFul intends to work with Digbi Health to develop the protocols for onboarding these patients, which will be similar to the Plan's requirements, and is open to coordinating these efforts with the Plan.

viii. OneFul has also evaluated other Soft-PBM solutions that meet the essential elements of this part of the RFI. There are web software solutions designed to perform the tasks of Pharmaceutical Benefits Management (PBM). These platforms offer a range of functionalities to manage pharmacy benefit programs. Here are examples:

- a. [McKesson's ProPBM: This software platform provides real-time pharmacy claims processing and gives PBMs full control over their pharmacy benefit programs<sup>1</sup>. It allows for the management of complex prescription drug formularies, varying co-pay schedules, accumulated pharmacy benefits, and drug utilization reviews \(DUR\), among other features.](#)
- b. **Encora's Automated Solutions:** Encora suggests that PBMs should transition to automated solutions to handle the evolving needs of the healthcare industry. [Their solutions offer robust and scalable architecture that supports web applications for all entities in the healthcare system, including cross-platform integration for billing, claims, eligibility processing, and formulary management.](#)
- c. These Soft-PBM tools are designed to streamline the administration of pharmacy benefits, ensuring compliance with healthcare regulations and providing cost-effective healthcare solutions.

- d. Large employers have used these tools to manage member health benefits. They are adaptable to programs such as weight loss, but likely need considerable software customization to address the weight-loss-specific program's programmatic requirements and processes.
- B. Potential for establishing a program outlining certain eligibility requirements, parameters, or other prerequisites for Plan members to follow in order to receive benefit coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for weight loss. As a result, the Plan seeks the ability to:
1. Require that an approved weight loss program or nutrition classes be completed before approval of payment for the medication.
  2. Develop step therapies involving lower cost medications.
  3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.
- i. OneFul's response to this portion of the RFI is the same as our response and recommendation in B-3 above, except for the following additional proposal.
4. Prohibit Body mass index (BMI) measurements from being estimated via telehealth visit to ensure accuracy and accountability, while enabling a data collection process that supports the successful implementation of the benefit.
- ii. OneFul proposes to qualify, inspect, and integrate a North Carolina network of physical locations and practices that can act as face-to-face patient centers for some member qualification functions, including but not limited to BMI assessment.
  - iii. In an initial pilot, OneFul proposes to work with Triangle area firms known to us that can provide patient pre-qualification testing, lifestyle assessment, dietary, and fitness profiling. OneFul would collaborate with the Plan to establish the criteria for qualifying these partner centers.
  - iv. In a first phase pilot program, some potential example partners in the Wake, Johnson, Durham, Orange, and Chatham county areas have been identified as potential partners to provide one-time services and follow-up or reassessment, including these:
    - [About Us - True You Weight Loss](#), Cary, NC, Dr Christopher McGowan
    - [Raleigh, NC Weight Loss Clinic | Programs by Doctors | North Carolina Weight Loss \(optionsmedicalweightloss.com\)](#)
    - [Medical Weight Loss in Cary, NC | Prejuve MedSpa and Wellness \(prejuvespa.com\)](#)
    - [Weight Loss & Wellness Clinic - Cary NC | Vitalize Wellness \(vitalizewellnessnc.com\)](#)
    - 3 to 7 other firms identified for due diligence and vetting.

C. Potential for establishing a program wherein the Plan has the flexibility to establish parameters for utilization management of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss, which may include considerations such as, but not limited to:

1. BMI;
2. Current weight;
3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity;
4. Documented enrollment and measurable participation in other nutritional or dietary programs;
5. Consideration of evidence for one or more comorbid conditions or other obesity- related medical conditions;
6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;
7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or
8. Any other considerations or parameters that would support a program in achieving the Plan's objectives of serving the members who need these medications the most?
  - i. Our top recommendation for such a system to meet these requirements to meet the plans is a system already developed, tested, and field-proven for managing the specific demands of an effective weight loss program. Based on our reviews of multiple systems and our research and due diligence, we recommend [DigbiHealth Inc.](https://digbihealth.com/pages/partner) ( <https://digbihealth.com/pages/partner> ).
  - ii. Other such systems may better match the Plan's needs and OneFul's. Our expert in web-based digital health systems is a Duke University neurobiologist and former CEO of BioMarker Labs, is a Bay Area, CA consultant with a considerable work history with OneFu. He is available to engage in a more extensive comparison and technical deep dive of some of the other systems once we better understand specific needs.
  - iii. The former co-founder of Digbi Health is a North Carolina native with extensive knowledge of the administrative challenges for effective weight-loss programs. If desired, we are discussing with him to fulfill a consulting role to work with OneFul and the Plan.
  - iv. We are familiar with several vendors of digital I.T. tools in addition to Digbi Health, which offer integrated remote monitoring of patients in weight loss programs using Internet of Things (IoT) methods to collect daily data. The pervasive use of continuous glucose monitors ('CGMs) is a critical tool to monitor adherence and provide critical alerts for adverse severe conditions. One of our advisors is the former manager of Abbott's Free Libre market-leading CGM. His consulting services will give in-depth direct application knowledge to collect real-world interactive data about patients' progress in a weight-loss or co-morbidity program for Type 2 Diabetes.

- v. As an illustration of the tools already developed and available in the Digbi Health system, here is a list of some of the screening, tracking, coaching, and follow-up tools provided by Digbi Health with its remote services:

## SCREENING

- Individuals can perform an **at-home gut biome and genetic test** to assess their digestive health and genetic predispositions.
- Monitoring **insulin levels** is made convenient with the use of **continuous glucose monitoring systems, which allow for the** real-time tracking of blood sugar levels.
- Comprehensive **risk analysis** is available, focusing on factors such as **obesity, gut health, and mental health** to provide a holistic health assessment.

## DEVICES & CONNECTIVITY

- A **glucose monitoring device** is provided to continuously track glucose levels, essential for managing diabetes.
- This device seamlessly **integrates with Apple & Google health** platforms, ensuring that health data is easily accessible and manageable.
- The system is **connected to your physician**, enabling them to monitor your health metrics remotely and provide timely advice.

## HEALTH COACHING

- Members have **12-month chat access to expert nutritionists, health coaches, and care teams**, offering personalized guidance and support.
- **Meal analysis** is tailored based on individual biology, ensuring dietary recommendations are optimized for personal health needs.

## CARE SUPPORT & CONTENT

- Comprehensive **health tracking** includes monitoring sleep patterns, stress levels, food cravings, and hormone fluctuations.
- Members gain **access to a private member community**, fostering a supportive environment for sharing experiences and advice.
- Various **food guides and a recipe planner** are available to assist in making informed dietary choices.
- A library of **self-help educational videos** is provided, covering various topics to empower individuals in managing their health.

- vi. Other potential companies with these types of services include [Noom](#), [RO](#), [Hims & Hers](#), [LifeMed](#), and others we have evaluated and are open to continuing to consider as partners.

**D. Provide cost, price structures, or other relevant expense information related to the recommendations and potential solutions submitted.**

- i. OneFul/TCP proposes "dosage-driven pricing" based on CoGs and cost to profitably dispense at a level to ensure that our facilities and staff fully meet all FDA and N.C. Board of Pharmacy regulatory requirements. Our pricing proposal will be agnostic to the indication to which it may be prescribed. Our professional PharmD staff and Quality Assurance shall reserve the right to review any prescription as per our standard operating procedure as regards the safety and any known interactions for a given individual patient and to reject any non-compliant formulations or orders.
- ii. OneFul/TCP acknowledges that the response to this RFI is understood not to be a response to a formal bid requested by the Plan. Further, OneFul/TCP is not committed to achieving specific pricing levels. However, we offer these achievable estimated pricing for standard dosing levels, which is feasible given today's market conditions and our business model:
- iii. Here is a Dosage Driven Pricing Example, which is our current estimate of the price to be charged to the Plan given the projected potential volumes of prescriptions, the current market conditions, bulk ingredient supplies, administrative costs of production, and specialized pharmacists, quality, and management labor:

<i>Wegovy Guidelines</i>			
<b>Obesity</b>	<b>Dose (mg)</b>	<b>Monthly Script Price*</b>	
Initial dose:	0.25	\$	105.00
Maintenance dose	1.25	\$	151.23
High dose:	2.40	\$	206.47
Maximum dose:	2.40	\$	206.47
<i>Mounjaro/ Zepbound Guidelines</i>			
<b>Obesity/TD Diabetes</b>	<b>Dose (mg)</b>	<b>Monthly Script Price*</b>	
Initial dose:	2.50	\$	110.00
Maintenance dose	5.00	\$	150.00
High dose:	10.00	\$	275.00
Maximum dose:	15.00	\$	400.00
*Subject to definitive procurement contract, volume, services, and administrative fees dependent			

## IV. PROFORMA EXECUTION PLAN

Our execution strategy incorporates proven methodologies, qualified personnel, known resources, and a responsive approach to managing deliverables. We use in-house expertise organized as a small project team with executive oversight to drive innovations and project execution. We work with known outside contractors and consultants with prior working relationships and high confidence in their work products for one-time and specialty functions.

### • Resources:

- Inhouse accredited 503A Compounding Pharmacy and licensed PharmD regulatory expert in cGMP operations.
- The current production capacity for GLP-1, GIP/GLP-1 is limited to approximately 4,500 monthly patients, primarily limited by trained personnel.
- The current bulk inventory of GIP-1, GIP/GLP-1 is only adequate to support an early pilot program plan for up to 500 patients per month, beginning in Q4 2024.
- Several qualified sources for these bulk API are either current vendors or identified alternative sources, though significant investment in inventory is warranted to meet the projected Plan's need.
- Two competing private equity firms have recently reviewed a facility and manpower plan to significantly expand the sterile processing capacity of TCP under 503B FDA Outsourcing Guidelines. These potential investors may offer additional resources, but constraints imposed by an investment agreement with them may compromise the Company's capacity.
- With the addition of a first phase of automation using identified commercial-off-the-shelf small-scale sterile automation, capacity in the current Cary, NC facility is projected to support up to 35,000 sterile product scripts/month with approximately 40 shifts of operations per month.
- OneFul/TCP has been pre-qualified by SBP Office Owner, L.P., a joint venture between Starwood Capital and Trinity Capital Advisors for a new purpose-built pharmaceutical grade facility in Morrisville NC in the Southport Innovation Center, which can be readied for occupancy by September 2024, further expanding development and patient customer service operations.
- Certified analytical laboratory services provided by [ARL](https://www.arlok.com/) (<https://www.arlok.com/>) are substantial to support large volume production of GLP-1 type product quality assessment, have been a long-standing partner certified by FDA FEI 3003644883 – registered and inspected as an analytical (chemical and microbial analysis) laboratory. <https://www.arlok.com>
- A network of advisors and healthcare professionals who have worked for the companies previously continue to be actively engaged and available to support a major project with the Plan as needed.

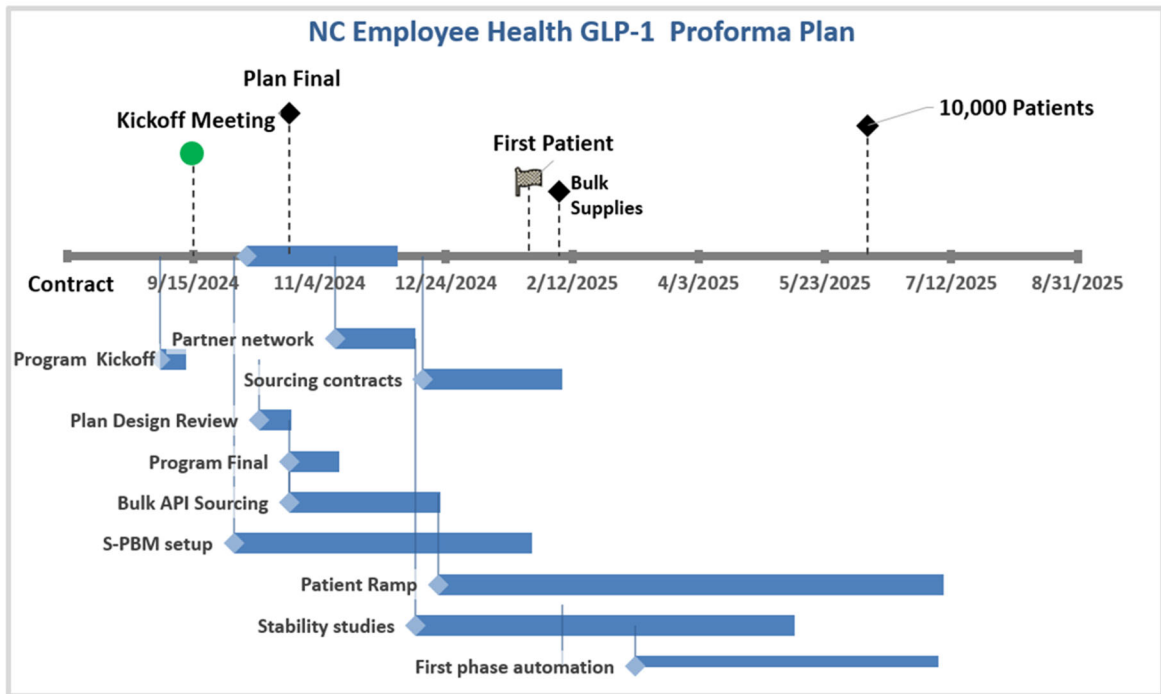
### • Project Management:

Our project methods include how the project will be developed, a proposed timeline of events, and reasons for why we suggest developing the project as described. We use formal and informal methods of project communication and management. Daily check-in of operating team members provides informal working communications. An administrative support lead keeps track of key milestones using Microsoft Project and online Monday project tools to initialize all known tasks, set schedule objectives, and track timelines weekly.



• **Proposed Project Schedule:**

The hypothetical example project chart below is based on concluding a binding contract with the Plan with a September 2024 project kickoff. The schedule will be updated upon receipt of a firm contract and order for the project.



## V. PROJECTED EXPENSES FOR PILOT PROGRAM

The following table is a non-binding budgetary estimate for the cost of a pilot program to support the Plan's goals as we perceive them from the basic outline of embedded in this RFI. For a limited number of Plan members with a rapid startup plan timing, the following estimate for services and materials is offered to discuss a possible definitive contract.

Services – Category 1	Estimated Contract Bid
Program design and review with Plan administrators, Project management and staffing to support Pilot goals	\$232,000.00
Collaborative development with 3 <sup>rd</sup> Party to configure, beta test, and implement a pilot Soft-PBM system supporting a limited number of member patients over a six to nine month timeframe	\$390,000.00
Provide additional GP1-product stability test data for pilot and ongoing product shipment within North Carolina to improve logistics and achieve cost goals.	\$280,000.00
Identification of qualified brick-and-mortar partners for in person member qualification, testing, and coaching for an initial pilot level program	\$84,000.00
<b>Total Services Costs</b>	<b>\$986,000.00</b>
<b>Working Capital Support Category #2</b>	
Procure adequate inventory of GLP-1, GIP/GLP-1 API to support the pilot program initially and ramp up to 10,000 patients/month by Q2 2025. Subject to pricing and sourcing negotiations, approximate, to be determined by end Q4 2024	
Deliver Two (2) Units	\$ <b>440,000.00</b>
<b>Total Development Contract Budgetary Estimate (Non-binding – For Discussion Purposes Only)</b>	<b>\$1,426,000.00</b>

*Disclaimer: The prices in the preceding table estimate the services and product specifications discussed. This summary does not guarantee the final price. Estimates are subject to change if project specifications or costs for outsourced services change before a contract is executed.*

## VI. OPTIONAL FUNDING REQUEST:

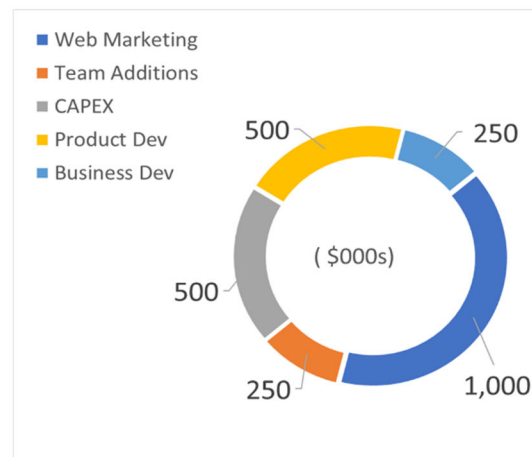
### OneFul/TCP Funding Plans

The following chart illustrates the financial plans of OneFul/TCP, which are critical for the Company to pursue investments in facilities infrastructure, capacity, and automation.

## Investment Goals

**Funds Raised to Date: \$7.1 M**

**Venture / Strategic – Q3 2024:**  
**Series A Preferred Shares**  
**\$5,000,000.**  
**Supporting capacity additions and new product development and trials**



**Projected Use of Funds  
Q1 2024 thru Q1 2025**

OneFul is receiving significant development funding from the U.K. National Health Service Innovation-UK fund for its personalized cardiovascular polypill product and technology licensing from U.K. partners. This funding does not support work on GLP-1 and weight loss programs but supports overall technical and intellectual property development.

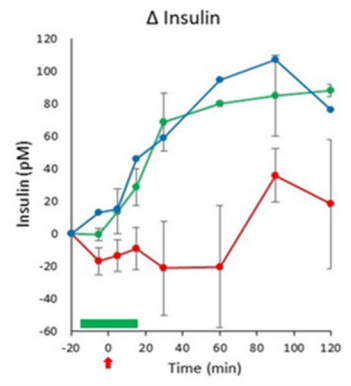
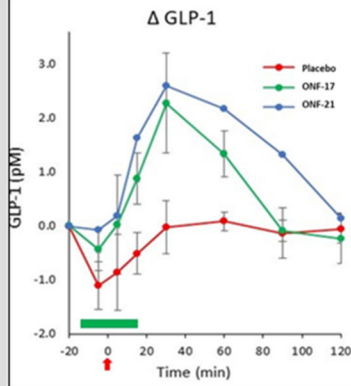
### GLP-OneFul complementary Development Support

Additional funding is expected from the UK NHS and IDC to support the GLP-OneFul concept product to complement the injectable products currently offered. See the included whitepaper describing this relevant product development. The Company would like to have a dialogue with the State of North Carolina about other funding resources that may be available to support this work that is related to the Plan's interest and future desire for sustainable and affordable cardio-metabolic health support.

Specifically, the Company requests information about the [N.C. Innovation Fund](https://ncinnovation.org/) (<https://ncinnovation.org/>) as a source to fund observational trials of the GLP-OneFul product under the auspices of UNC Health researchers and a potential program for childhood obesity with the UNC Children's Research Institute. Information and guidance about other funding programs for small business enterprises that may support our developments and growth capital requirements may also underpin the Plan's goals are requested.

## GLP-OneFul™ Concept Product Development:

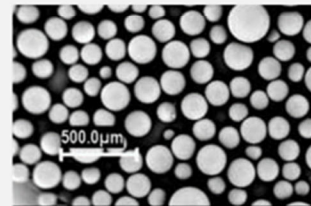
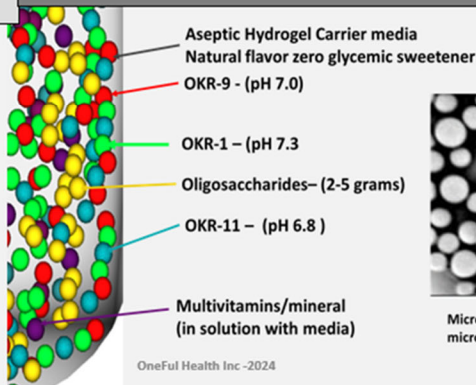
- Endogenous GLP-1 agonists
- Micro-encapsulated actives
- Oligosaccharides for microbiota
- Nutrients for general nutrition
- Minimal adverse side effects
- Post-semaglutide/terzepatide weight loss/ diabetes maintenance
- Obesity therapy in children potential first application



Active Ingredients micro-encapsulated and coated for sustained GLP-1, PYY release in distal colon for 8 to 12 hours



50-gram squeeze pouch, shelf stable, flavored



Microcapsules average diameter of 700 microns, 30-35% API loading

OneFul Health Inc -2024

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## APPENDIX OF SUPPORTING MATERIALS (FOLLOWING PAGES)

# The History and Current Burden of **Medically Managed Weight Loss**



While modern sedentary lifestyles and heavily processed diets have certainly contributed to **74% of Americans being overweight or obese**, weight management has always posed a global challenge.<sup>1</sup> Maintaining a normal weight is paramount to living a healthy, happy, and productive life as overweight and obesity are greatly associated with the leading causes of death - heart disease, stroke, and diabetes.<sup>2</sup>



Medications for weight management have a long history. In the 18th century, people relied on soaps and vinegars as forms of purgatives. In the late 19th and early to mid-20th century, doctors began prescribing thyroid hormones, dinitrophenol, and amphetamines for weight loss until the side effects became apparent.<sup>3</sup>

Following that, derivatives of amphetamines such as phentermine and other serotonergic drugs and monoamine reuptake inhibitors were prescribed for weight-loss in the 1950s.<sup>4</sup> All of these drugs were tested and approved by the FDA in 1973, meaning they were not approved using the modern safety standards that we employ when studying pharmaceuticals today.<sup>5</sup>

After patients experienced limited weight loss and severe adverse effects from these medications, the American Association of Clinical Endocrinologists and the American College of Endocrinology stated that lifestyle modification - consisting of a reduced-calorie diet and increased physical activity - is the most effective and healthiest strategy for weight management.<sup>6</sup>

Despite lifestyle behaviors having the greatest impact on one's weight, pharmaceutical companies continued formulating and developing weight management drugs, with the FDA approving the first drug for weight management in 2021 since 2014.<sup>7</sup>

# The Challenges with **Medically Managed Weight Loss Programs**

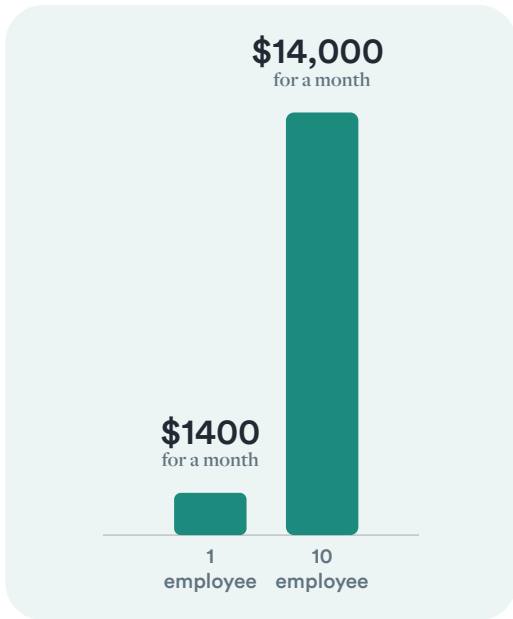
## Cost

According to a study from Kaiser Family Foundation, *employer-based health plans cover 42% of all prescription drugs*<sup>8</sup>. Pharmaceuticals are the number one expense for employers, and that expense positively correlates to the cost of the drug.

Furthermore, Kaiser Family Foundation found that a small number of drugs account for a disproportionate amount of total drug costs<sup>9</sup>. In fact, the top 5 most expensive drugs account for at least 10% of total prescription drug spending amongst employers.<sup>10</sup>

Source : [3]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[4]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[5]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[6]<https://pro.aace.com/disease-state-resources/nutrition-and-obesity>

[7]<https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
[8]<https://www.kff.org/medicare/press-release/https-www-kff-org-medicare-press-release-new-analysis-compares-prescription-drug-spending-and-use-across-large-employer-plans-medicare-and-medicaid/>  
[9]<https://www.benefitspro.com/2019/05/21/10-drugs-topping-employers-plans-pharma-spend/>  
[10]<https://www.benefitspro.com/2019/05/21/10-drugs-topping-employers-plans-pharma-spend/>



*Average cost of GLP-1 drugs*

*The 2020 National Health Expenditures revealed that employer health expenditures grew in 2020 at the fastest rate of growth since 2002.<sup>[1]</sup>*

Should these weight-loss drugs become widespread amongst employees, employers will be faced with covering extremely expensive GLP-1 drugs that average about \$1400 (depending on which drug) for a month's supply of weekly injections. If an employer now has to cover 10 employees GLP-1 medications, that costs them an extra \$14,000 a month on just ten employees.

## Care

Even worse, out of those ten employees, not all will see results, and those who do, will have to make serious lifestyle changes to see continued results.

Ultimately, these GLP-1 medications add yet another medication into **overflowing pill cabinets and fail to address the root cause of obesity**. Instead, employers should focus on empowering their employees with the knowledge to create positive lifestyle change that moves beyond managing symptoms and actually targets the root cause.

“

*Patients still need to eat healthily, work out, and keep in touch with a professional who can monitor their progress and tweak their program. The U.S. medical system isn't exactly set up for that kind of personalized medicine, and doctors aren't immune from biases about weight gain.”<sup>[2]</sup>*

**Ethan Lazarus**

Obesity Medicine Association President

Source : [1]<https://www.cms.gov/newsroom/press-releases/national-health-spending-2020-increases-due-impact-covid-19-pandemic>  
 [2]<https://www.bloomberg.com/news/features/2022-01-04/prescription-weight-loss-drugs-for-obesity-work-if-your-doctor-lets-you-get-them>



# A Sustainable Solution to America’s Obesity Epidemic: **Incorporating Genetics and Gut Microbiome to Personalize Weight Care**

Digbi Health — a caring and innovative personalized digital therapeutics company — harnesses gut microbiome, genetics, and digital care to treat the root cause of obesity and empower members with knowledge to sustainably lose weight without the aid of a lab-made pharmaceutical.

When employers sign up with Digbi, each employee submits an *oral swab and fecal sample along with demographic and lifestyle information*. Using test results and AI predictive modeling, Digbi suggests each employee make small but impactful changes to their personalized food and lifestyle, ultimately reducing or reversing their symptoms. Digbi also provides 1:1 coaching, digital content, and a vibrant member support community.

By using food as medicine, Digbi’s coaches teach each members what foods are best for their body and why based on their unique gut and DNA.



*No two people have the same genetic and gut microbiome make-up, so no two people should receive the same recommendations.*

**Ranjan Sinha**  
CEO and Founder of Digbi Health

75% of Digbi members have lost weight through our program, and over 30,000 pounds have been lost collectively amongst our members over 3 years. *By treating the root cause of obesity - the gut microbiome - members also report improvements in*





**89%**

Digestive Disorder Symptoms

**75%**

Insomnia/Sleep Disorders

**66%**

Depression/Anxiety

**66%**

Chronic Inflammatory Pain

**50%<sup>13</sup>**

chronic acne/eczema

*Empower your employees to take greater control of their health destiny by helping them address the root cause of their obesity.*

## To learn more information

Contact Us  
at [hello@digbihealth.com](mailto:hello@digbihealth.com)



# An Overview of **Weight Loss Medications**

There are currently five medications currently approved by the FDA for chronic weight management. Two of them are approved for long-term use, and the other three are approved for short-term use (less than 12 weeks). While they all work differently and have different side effects, all five categories share one thing in common: they must be used in addition to a reduced calorie diet and increased physical activity.<sup>14</sup>



## **Wegovy / Semaglutide**

In June 2021, The FDA approved Wegovy - *an injection approved for chronic weight management in adults* who are obese or overweight with at least one weight-related chronic condition. Wegovy works by mimicking a hormone called glucagon-like peptide-1 (GLP-1), and they increase satiety and have a regulatory effect on glucose homeostasis through the reduction of blood glucose levels and insulin release.<sup>15</sup> It is a higher dose version of the diabetes drug Ozempic, which

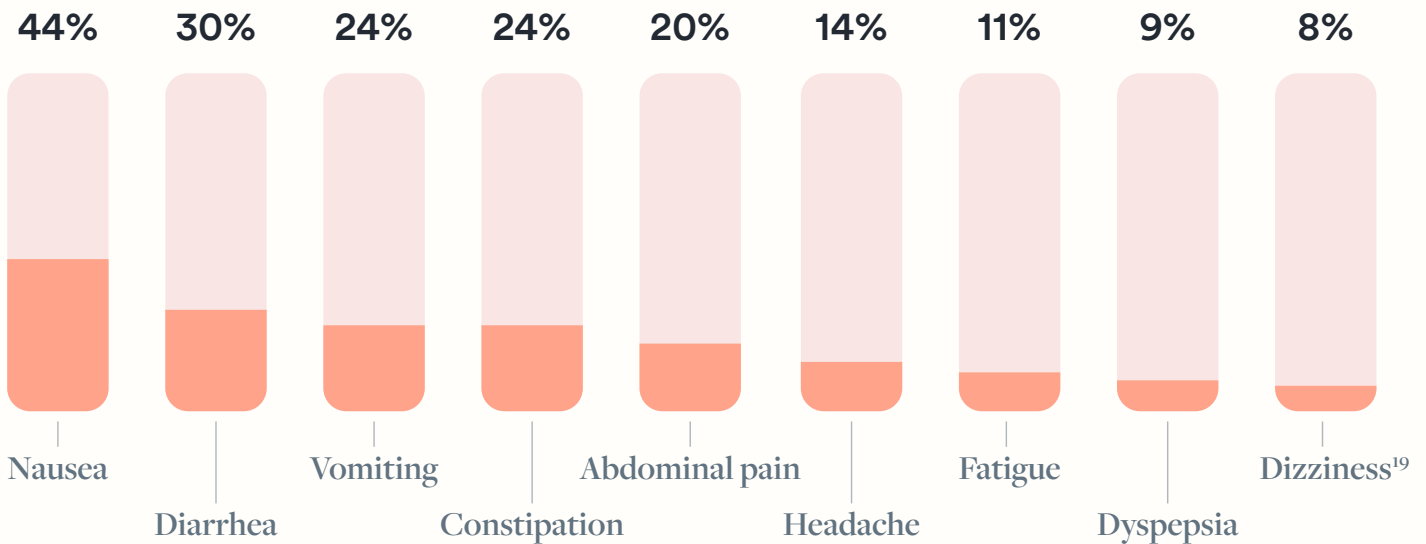
Source : [13] <https://news.blueshieldca.com/2020/07/15/more-than-23-500-blue-shield-of-california-members-reclaim-their-health-in-first-year-of-reimagined-wellvolution-program>  
[14] <https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
[15] <https://pubmed.ncbi.nlm.nih.gov/2726901/>



continues the trend of manufacturers repurposing diabetes drugs for other conditions common in diabetic patients.<sup>16</sup> Wegovy must be dosed one a week long-term.

Wegovy was approved by the FDA after four 68-week trials.<sup>17</sup> 33% of the patients lost more than 20% of their body weight during the 68 weeks, with the average being 15% body weight loss.<sup>18</sup> Compared to the other four categories of weight loss drugs, Wegovy resulted in the greatest weight loss.

### Wegovy causes many *adverse side effects*:



### Saxenda

The second most common weight loss medication is Saxenda. Like Wegovy, it is also a GLP-1 antagonist involved in the regulation of energy balance and activation to reduce food intake and thus body weight<sup>20</sup>. In other words, Saxenda is a synthetic version of a satiety hormone that makes you feel full.

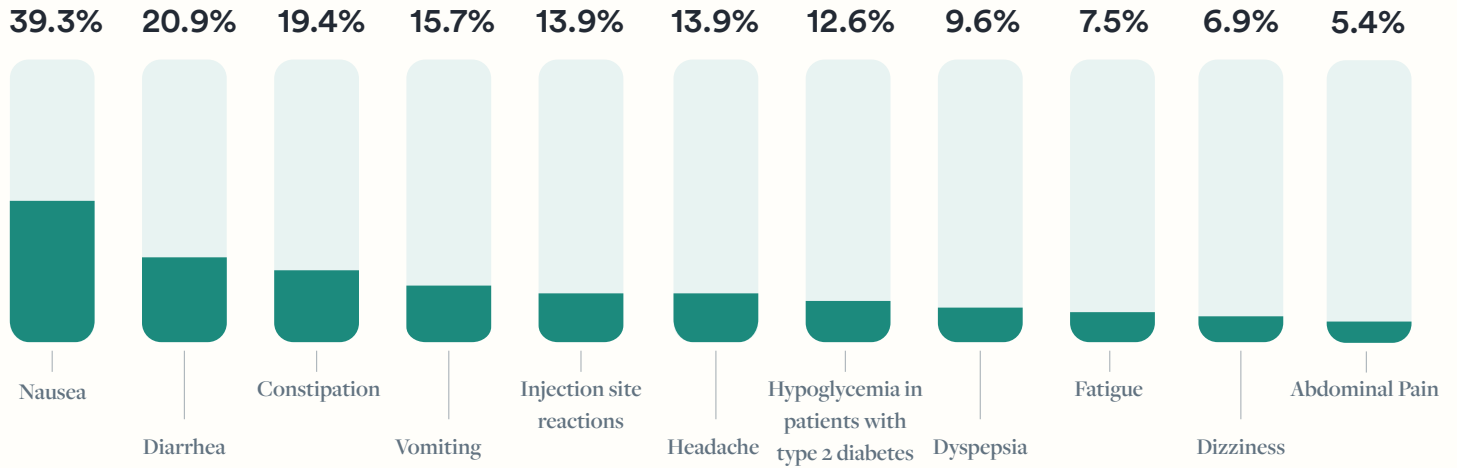
Similar to Wegovy, Saxenda injections must be administered weekly (long-term), with an *average monthly cost of \$1,300 without insurance*.<sup>21</sup> Though slightly less promising than Wegovy, Saxenda still produces a 9% body weight loss, which contributes to about 17-18 lbs after 1 year.<sup>22</sup>

Source : [16]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
[17]<https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
[18]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
[19]<https://www.drugtopics.com/view/a-review-of-fda-approved-medications-for-chronic-weight-management>

[20]<https://pubmed.ncbi.nlm.nih.gov/2726901/>  
[21]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
[22]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>



Of the people using Saxenda, these percentages *experienced the following adverse effects:*



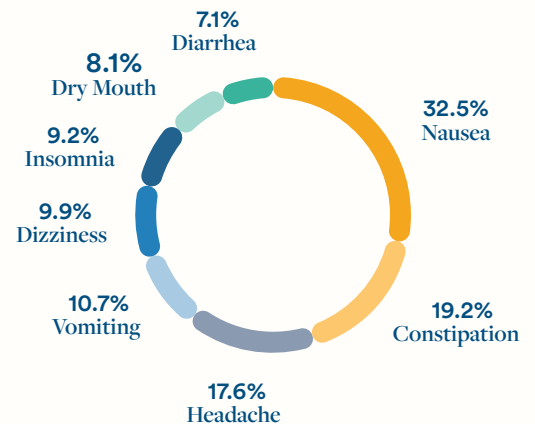
### Naltrexone ER / Bupropion ER (Contrave)

The third weight loss medication approved by the FDA is Naltrexone ER / Bupropion ER (Contrave). Naltrexone is an opioid antagonist, and bupropion is a dopamine and norepinephrine reuptake inhibitor. Before approved for a weight loss drug, *bupropion was approved for depression and smoking cessation*<sup>23</sup>. Bupropion reduces appetite through adrenergic and dopaminergic pathways in the hypothalamus.

Bupropion is only approved for short-term use (less than 12 weeks). Compared to the two Semulgitide’s previously mentioned, Bupropion is less effective, causing lower rates of weight loss.

*Bupropion is incredibly dangerous in patients with hypertension as it increases blood pressure. It also has the following negative side effects:*

The box also warns it can increase suicidal thoughts and behaviors.<sup>24</sup>



Source : [23]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[24]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>

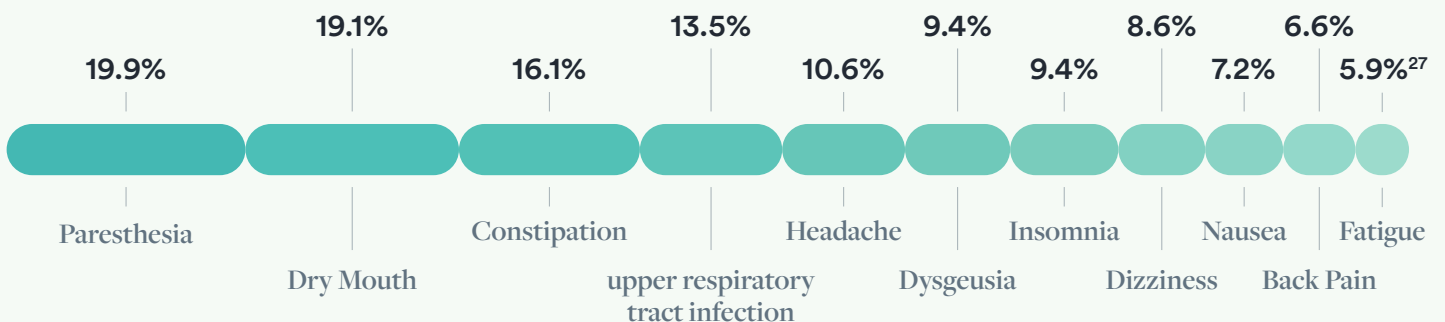


## Phentermine / Topiramate ER (Qysmia)

Phentermine was approved for short-term use by the FDA in 1959, but is still a commonly prescribed anti-obesity medication.<sup>25</sup> It is a derivative of amphetamine, meaning it's a controlled substance and stimulant. Phentermine works by releasing catecholamines in the hypothalamus which decreases appetite and food intake, thus enhancing satiety<sup>26</sup>.



*Like all the other weight loss medications previously mentioned, Qysmia also has adverse side effects:*



Source : [25]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
 [26]<https://www.forbes.com/sites/joshuachen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
 [27]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>

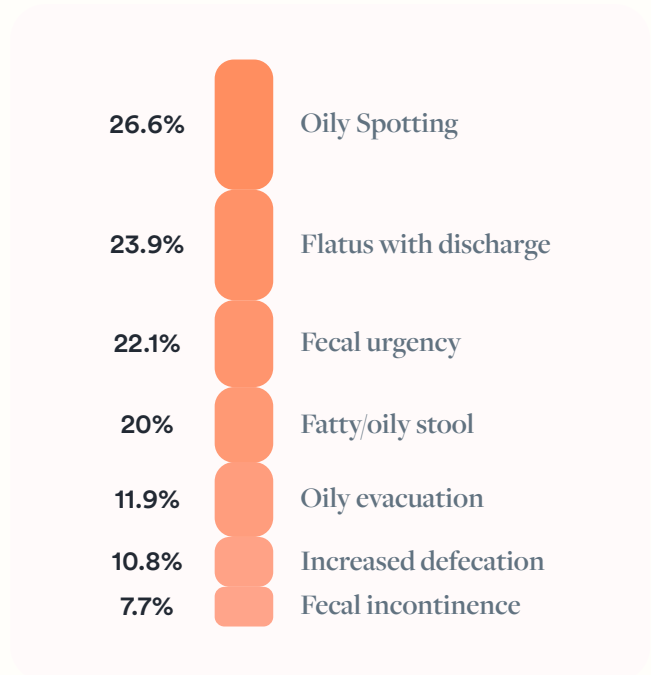



## Orlistat

Orlistat is the only chronic weight management medication available both over the counter and by prescription. Orlistat works by inhibiting gastrointestinal lipases, which results in decreased fat absorption. Patients on Orlistat must adhere to a reduced calorie diet that contains about 30% of the calories from fat.

*Even though Orlistat can be purchased OTC, **it still comes with a host of side effects:***

*Other warnings: decreased absorption of fat-soluble vitamins, severe liver injury, increased GI pain in people with high fat diet, warning for organ transplant as it interacts with immunosuppressants.*



## **Better than GLP-1 Drugs: *Are Endogenous GLP-1 Medical Foods Possible?***

Edison Hudson, CEO, Founder [LinkedIn](#)  
OneFul Health Inc,  
Research Triangle Park, NC

According to Science, the 2023 Breakthrough of the Year was developing and adopting glucagon-like peptide-1 (GLP-1) agonists, branded as Wegovy, Zepbound, Mounjara, etc. The studies showing that these new long half-life injections produce 15 to 20% weight loss are impressive and good news. In November, a study of obese patients with cardiovascular complications using these products showed a 20% lower risk of heart attacks and strokes. An excellent summary of the potential health impact of these GLP-1 agonist drugs by the American Academy for the Advancement of Science is in this video. <https://youtu.be/QnmMSMF7wO4>

Holden Thorpe, editor-in-chief of Science, points out there are "More Questions Than Answers" (<https://www.science.org/doi/10.1126/science.adn3693>) about the promise of these drugs. The American College of Cardiology summarized the practical barriers to realizing these benefits, including prices over \$1,000 a month, poor insurance coverage, lack of physician familiarity, and shortages. A Journal of the American Medical Association report highlights how these drugs further exacerbate US healthcare inequality, as their benefits are mostly going to the well-heeled or insured, leaving out the very populations most affected by cardio-metabolic chronic disease.

Nevertheless, patient demand has gone viral, and the [GLP-1 agonist Drug Market is Exploding](#). Some are predicting that this drug class will become the Greatest of All Time.

[OneFul Health Inc.](#), is initially committing to this GLP-1 revolution by investing in bulk inventory of the FDA-approved form of semaglutide, the active ingredient of popular drugs Ozempic and Wegovy. Our accredited sterile pharmaceutical facility, [Triangle Compounding](#), is now filling patient prescriptions from our physician, clinic, and hospital providers with semaglutide and tirzepatide, and will support other supplies are tested.

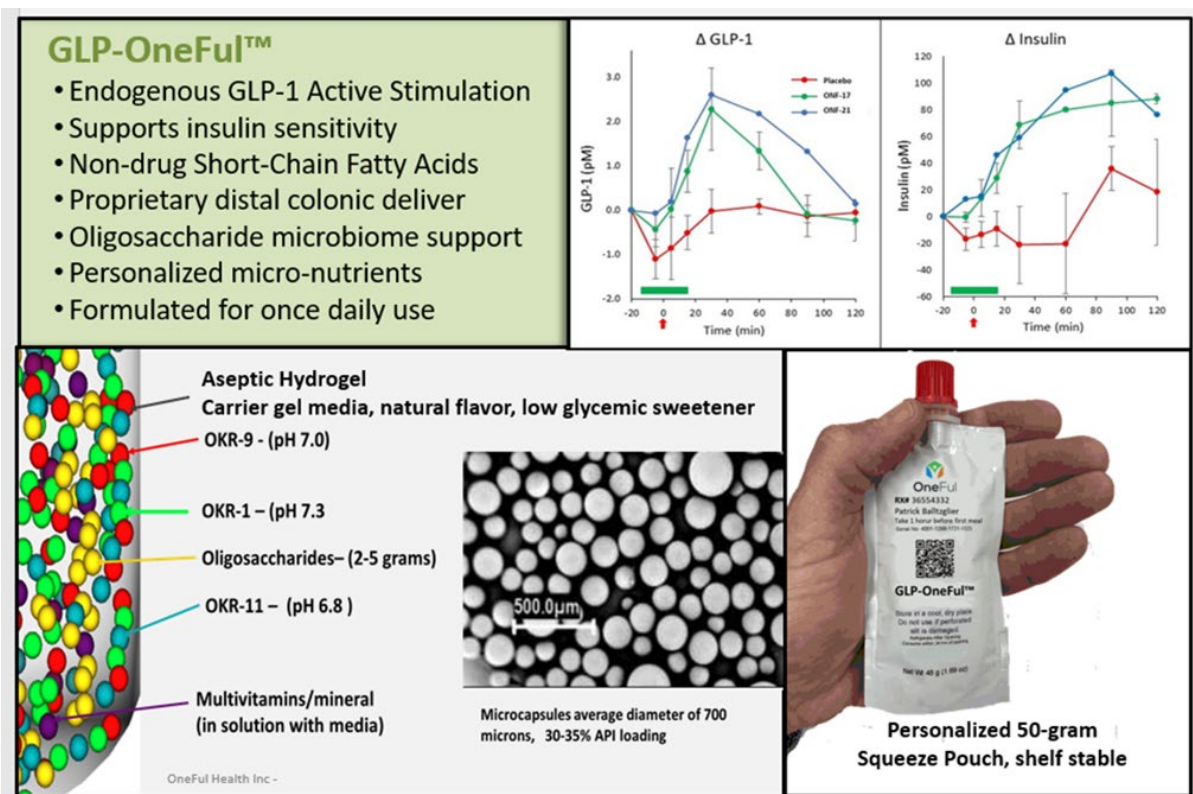
OneFul possesses technologies that enable the delivery of high doses of active ingredients to specific regions of the digestive system. Using a patent pending method of micro-encapsulation, OneFul can capture active ingredients, including short-chain fatty acids ('SCFA's'), and some amino acids that have been shown in multiple research publications to stimulate GLP-1 and other satiety hormones, naturally.

The research cited below, shows that when these acids are delivered to the distal colon in sufficient quantity, GLP-1 production by the L-cells that are prevalent there, naturally produce significant levels satiety hormones.

OneFul is also exploring the development of complementary treatments to the GLP-1 agonists drugs, based on recent GLP-1 incretin science. In November, OneFul completed the buy-back of [Panaceutics.com](http://Panaceutics.com)'s assets, a personalized nutrition and clinical foods supplier. Panaceutics has successfully scaled up the production of relevant formulations for microbiome support using OneFul's patented robotic personalization automation. In snack-sized (50-gram) squeeze pouches, these products have delivered multiple gram-level doses of active ingredients known to create small-chain fatty acids (SCFA). Several different SCFA stimulate significant levels of [endogenous GLP-1 in the human gut](#).

We have formulated and are planning to test this concept, which uses only FDA listed Generally Recognized as Safe ingredients, along with specialized oligosaccharide fibers that stimulate the microbiota of the gut, promoting higher insulin response and slowing food transits through the gut, reducing appetite.

OneFul conjectures that using its additive manufacturing platform to combine high doses of several SCFA promoting ingredients, along with other nutrients important to



the intestinal epithelial layer, might be able to produce the sustained release of natural GLP-1 and other satiety hormones. Over the past two decades, multiple animal and human research publications have pointed to the substantial stimulation of GLP-1 levels when ingredients that are generally recognized as safe (GRAS) are released for a sustained time in the correct segments of the intestines and colon. Other GRAS plant ingredients have been shown to suppress DPP-4 enzymes, which degrade the effects of GLP-1. Also well documented, even with the GLP-1 mimic drugs, is that many people respond differently, have different levels of adverse side effects, linked to the dosage levels of the treatment, and corresponding to age, sex, and diet, so likely making personalized treatment critical to effectiveness.

An evidence-based formulation and trial of personalized medical foods could be an approach that might lead to an effective, low-cost, and patient-centric treatment for diabetes (T2DM) and other metabolic diseases. Such complementary products may not be as powerful or have the long half-life of the injections, but they may assist those you have stopped the drugs and desire a long-term product that can help keep weight off, and glucose levels in better check. Products that are personalized, easy to integrate into daily life, and affordable would be ideal. Efficiently made-to-order with robotic automation, such products could be sold profitably at below "pumpkin-spice latte" prices. Medical foods prescribed to serve individual patients' metabolic and economic needs could answer many questions hindering the full healthcare value of the GLP-1 agonist breakthrough.

**Sources:**

- [Obesity meets its match \(science.org\)](https://www.sciencemag.org/obesity)
- [American College of Cardiology Summary Of GLP-1 Treatment Barriers](https://www.ahajournals.org/doi/10.1161/aha.116.312111)
- [Racial, Ethnic, and Socioeconomic Inequities in Glucagon-Like Peptide-1 Receptor Agonist Use Among Patients With Diabetes in the US](https://www.diabetesjournal.org/doi/10.2337/diabetes.2019.0150)
- [GLP-1 agonist Drug Market is Exploding](https://www.fiercebiotech.com/analysis/2019/08/20/19082001)
- [Short-Chain Fatty-Acid-Producing Bacteria: Key Components of the Human Gut Microbiota](https://www.nature.com/articles/s41564-019-0548-4)
- [Exploratory clinical studies of GRAS compounds in Type 2 diabetes patients, conducted at Carolina Research, gastrointestinal research clinic in Greenville, NC](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6788881/)
- [Functional foods-based diet as a novel dietary approach for management of type 2 diabetes and its complications](https://www.mdpi.com/2077-0383/11/12/2211)
- [Mechanisms to Elevate Endogenous GLP-1 Beyond Injectable GLP-1 Analogs and Metabolic Surgery](https://www.sciencedirect.com/science/article/abs/S0014299819300011)
- [Gut Microbial Signatures for Glycemic Responses of GLP-1 Receptor Agonists in Type 2 Diabetic Patients: A Pilot Study](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6788881/)

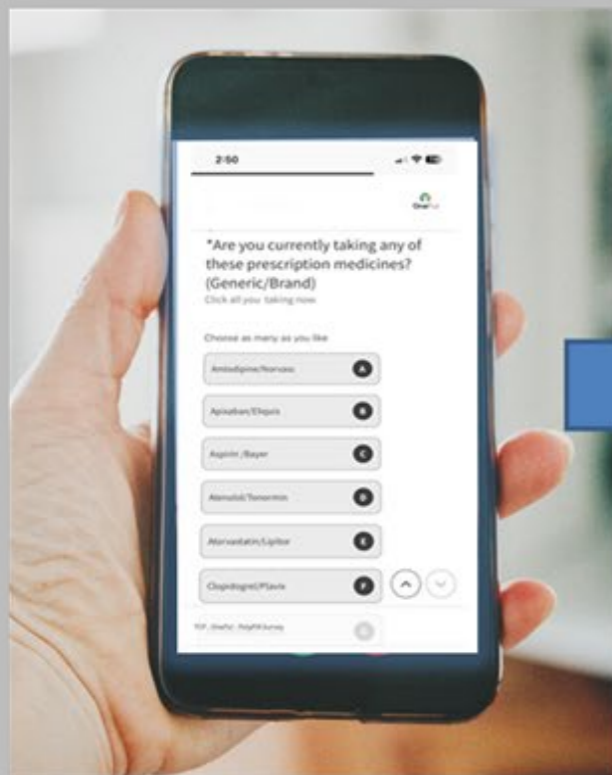




*Making Medicines Work Better For EveryONE*

*Edison Hudson, CEO & Founder*

*[www.OneFul.Health](http://www.OneFul.Health)*



**Online Patient Screening**

**Telemedicine Consults  
& Prescriptions**

**Robotic Made on Demand  
Combinations**

**Delivered Direct  
to Patients**

## **Pharm-Tech for Personalized Cardio-Metabolic Disease Prevention**

# Who We Are:

## Modernized Compound E-Pharmacy With Patented Pharm-Tech

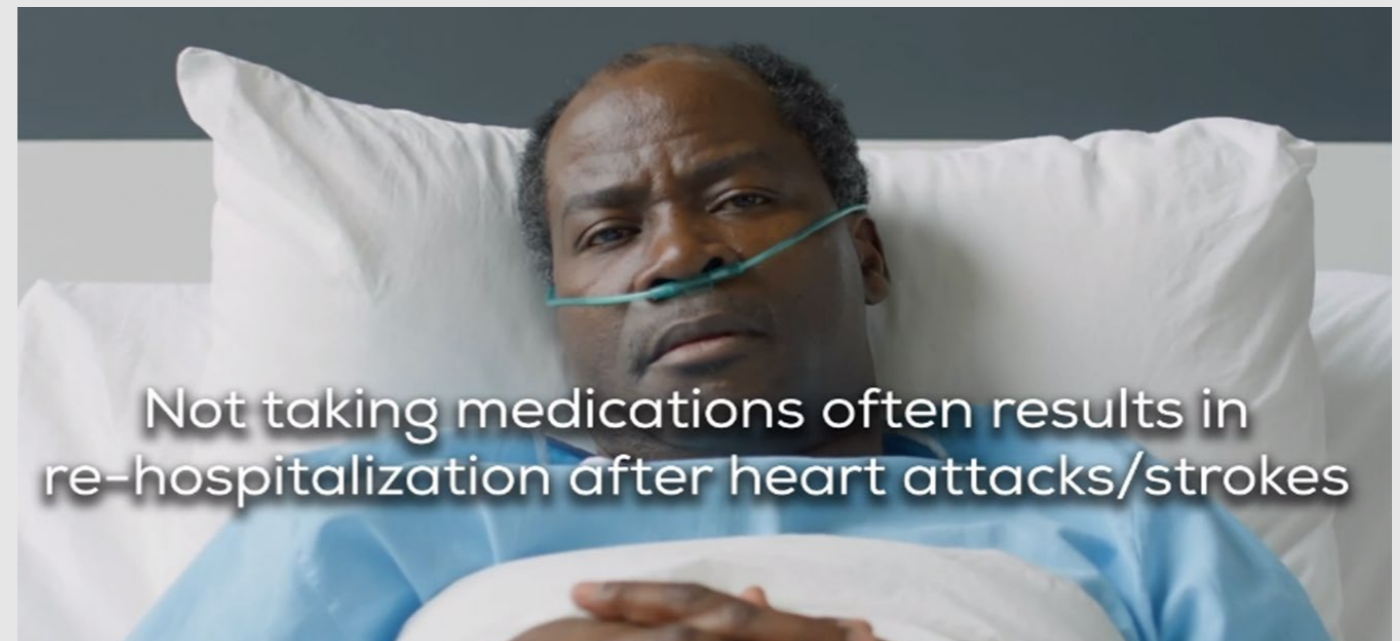
- Personalized Therapies for Chronic Cardio-metabolic Conditions
- Initial focus is Prevention of Heart Attacks/-strokes
- Clinically-Proved 'Polypill' Strategy Significantly Improves Adherence
- Precision to Individual Metabolism with Pharmacogenomics, Micro-dosing
- Low Regulatory Risks - Only Approved Drugs, safe Actives, Automated cGMP
- Low Costs – Uses Lab Certified Generic Drugs with Block-chain Tracking



# Key Problem Focus:

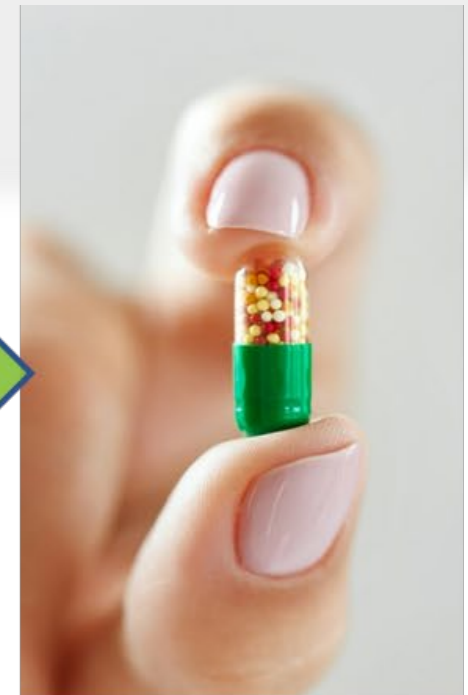
## *Non-Adherence to Medicines*

- More than half of adults over 65 (54%) report taking four or more prescription drugs
- CVD drug therapies typically require 3-7 pills per day, with adherence less than 50%
- Costs of many medicines prevents those who need them most from staying on them
- Non-adherence costs US Healthcare over \$300B annually

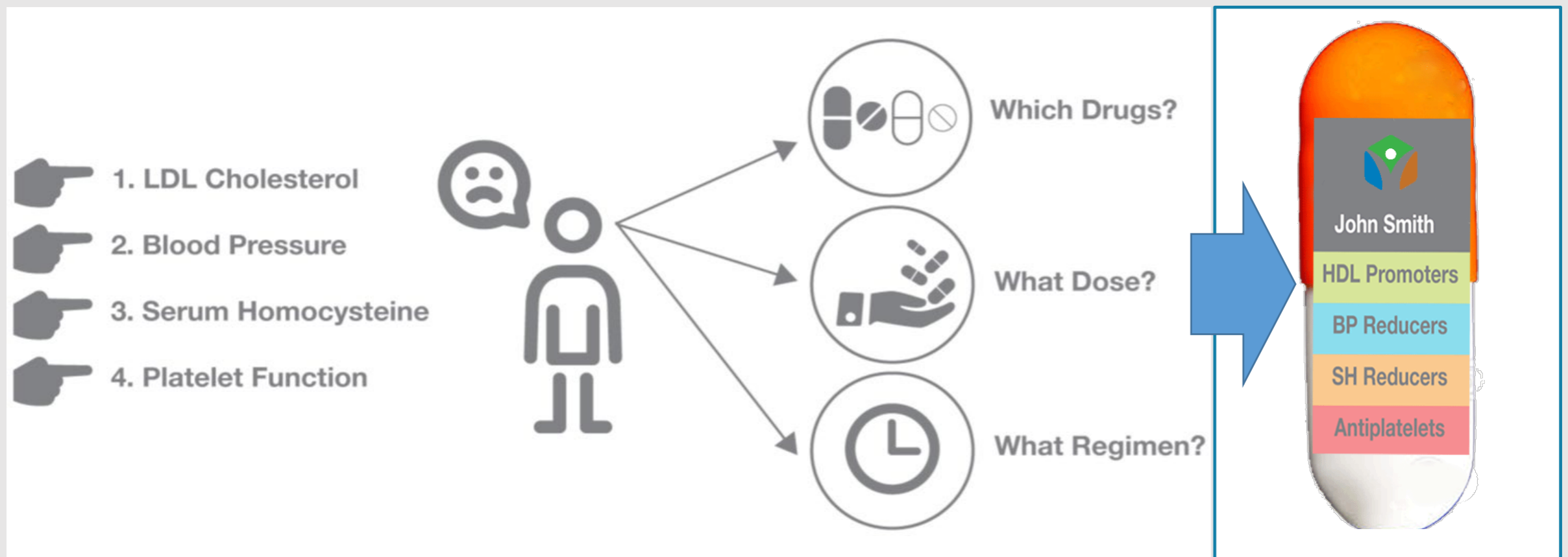


# New Solutions for Huge Needs: Chronic Cardio-Metabolic Prevention

- Aging demographics, underserved populations, and “self-insured” healthcare systems drive the market demand for low-cost therapies
- Physician prescribed combinations of approved medicines reduces medication errors, frustration, lowers costs



# Polypills Have Shown Clear Outcome Benefits<sup>1</sup>: Targets several key cardiovascular disease ('CVD') risk factors<sup>2</sup>:



1) American College of Cardiology – [‘One Pill for Them All: Polypill Therapy for the Prevention of Cardiovascular Disease’](#)

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# Our Complete Platform:

## *Precision Cardiovascular and Metabolic Prevention Medicine*



### Digital Twin Profile :

- Age/Sex/Race
- Genomic
- Biomarker Tests
- History
- Prescriptions



### Pharmacists with AI:

- LDL Cholesterol
- Blood Pressure
- Serum Homocysteine
- Kidney / Liver markers
- Platelet & Coagulation



### Digital Formula :

- Which Drugs?
- What Dose?
- What Schedule?

**CVD-P<sup>3</sup>**

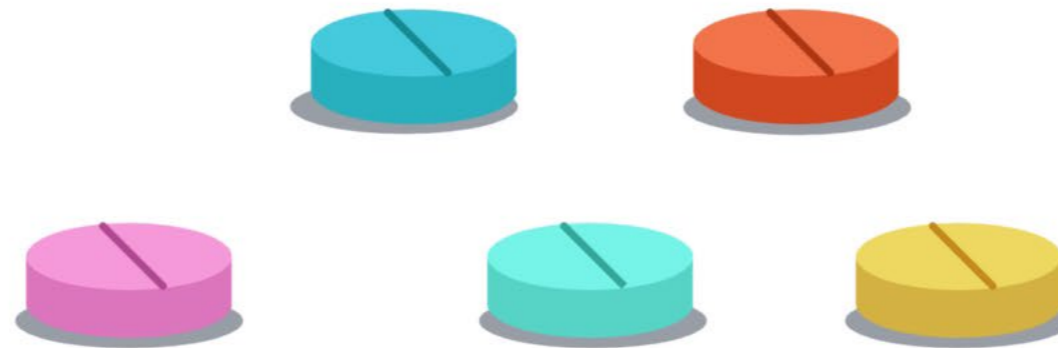


**Precision  
Prevention  
Polypill**

# How We Do This:

- 3 to 7 Purified APIs
- CoA for each bulk batch by outside lab
- Only Active Ingredients
- Compacted In a Single Small Capsule (1,0)

OneFul's  
Personalized  
Polypill



# Why Now:

## To Be First To Market with Precision Polypill

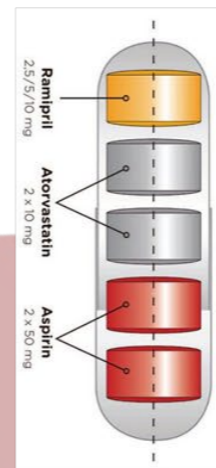
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OneFul Designs First Personalized CVD Polypill

2019

SECURE Polypill Study



2022



WHO Lists PolyPill as Essential

2023



AI -Based Clinical Decision Aids

2025+



# Cardiovascular Polypill Formulations: Initial Pharmacopeia

- Initial limited set of API's addresses over 70% of CVD medical protocols
- Supports standard & custom dosages to match physician's script, published bioequivalence/safety data
- Additional APIs in pipeline as sourcing, patent expirations allows (example Apixaban/Eliquis)

Generic API	Mechanism of Action	OneFul Supported Doses* (mg)	Fixed Doses			Personalized Doses		
			Primary (PolyPill Ltd-UK)	Primary (PolyCap-India)	Secondary (Trinomia - EU/UK/CA)	CABG (Advent Health)	Post Stent (UNC Health)	Early Stage Heart Failure (Mayo)
lisinopril	ACE inhibitor	5mg / 10mg / 20mg				12.5/25/50	12.5/25/50	
ramipril	ACE inhibitor	2.5mg / 5mg / 10mg		5				2.5/5/10
losartan	ARB	25mg / 50mg	25		25/50			
aspirin	Anti -Platelet	81mg / 100 mg		100		81	81	
clopidogrel	Anti -Platelet	75mg			100	75	75	
metoprolol	Beta Blocker	25mg / 50mg /100 mg				25/50/100	25/50/100	
atenolol	Beta Blocker	25mg / 50mg /100 mg						25/50/100
amlodipine	Calcium-C blocker	2.5mg / 5mg	2.5					
hydrochlorothiazide (HCTZ)	Diuretic /Anti Edemic	12.5 mg / 25mg	12.5	12.5				12.5/25
atorvastatin	Statin	10mg / 20mg / 40mg		20/40	20/40		10/20/40	
rosuvastatin	Statin	10mg / 20mg / 40mg	10			10/20/40		
simvastatin	Statin	10mg / 20mg / 40mg						10/20/40

# Accurate, Safe, Affordable:

- CVD-P<sup>3</sup> Costs with labor < \$0.30 per 5 drug polypill
- Enables profitable products at out-of-pocket costs as low as \$1/day
- Out-of-pocket to costs close to average US health care co-pays for five separate drugs



## Enabled by Our E-Pharmacy Platform:

- Robotic “Drug Toner Cartridges” design
- Accredited 503A/B Facilities
- Telemedicine cardiologist prescribers



**Low CAPEX, small footprint systems yields rapid ROI to support regional facilities reducing DTC shipping costs**

# PolyPill Capsule Automation Platform – (Gen 1)

- Compact work-center, 250 ft<sup>2</sup>
- 5 independently dosed and compacted APIs or blends
- 1,800 multi-API polypills / hour
- Automated bulk capsule load/open/close/eject
- Rapid changeover API cartridges
- Minimized cleaning
- Negative Pressure enclosure
- Two fillers controlled from single supervisory console



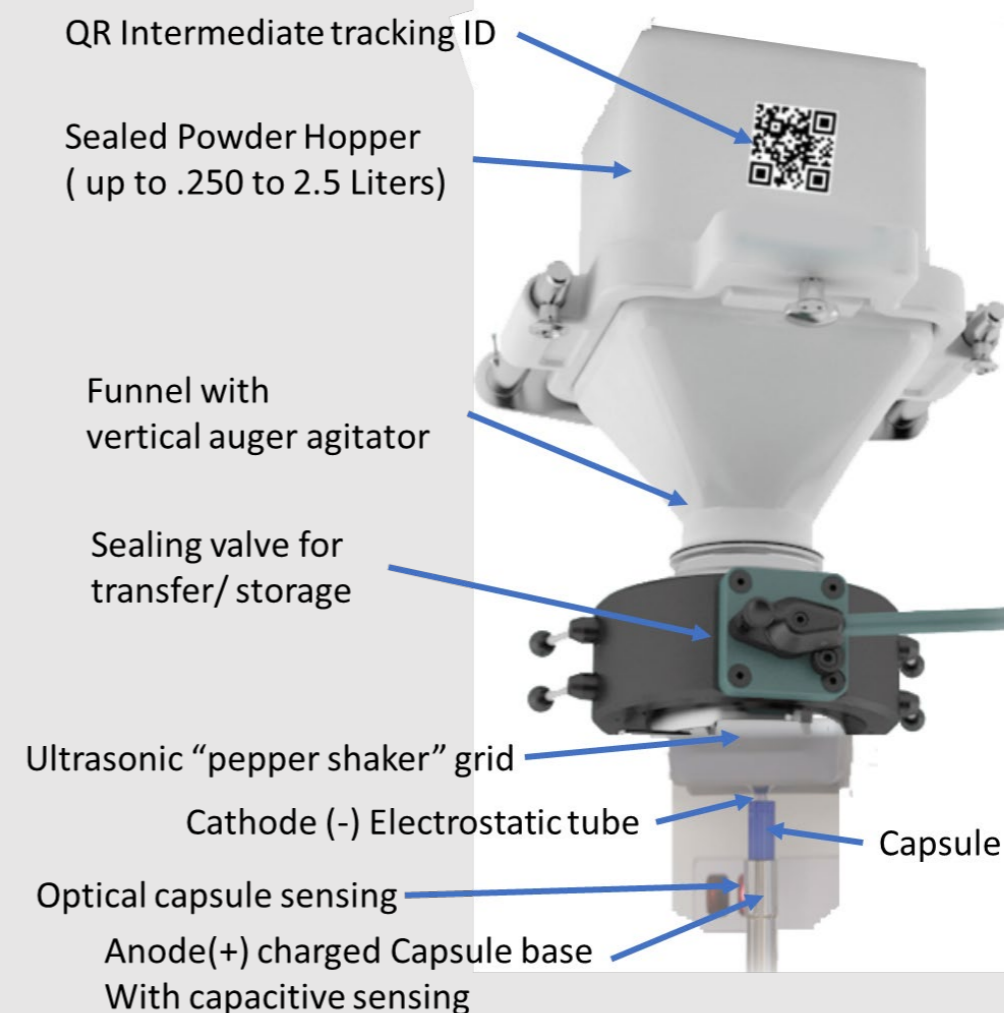
**Low CAPEX, small footprint systems  
yields RoI less than 6 month**

# Key Innovation:

## Digital Micro-dosing Electrodynamic Cartridge 'DMEC'\*

### Digital Drug 'toner cartridge'

- Up to five DMEC dosing heads per filler
- 5-7 APIs onboard concurrently
- Dosing accuracy to 0.1 milligram
- 150 mg/sec powder dispense (v1.0)
- Closed loop dosage measure & logging
- API validation and tracking via block-chain linked QR coding
- CE certification, cGMP SoPs, IQ/OQ documentation

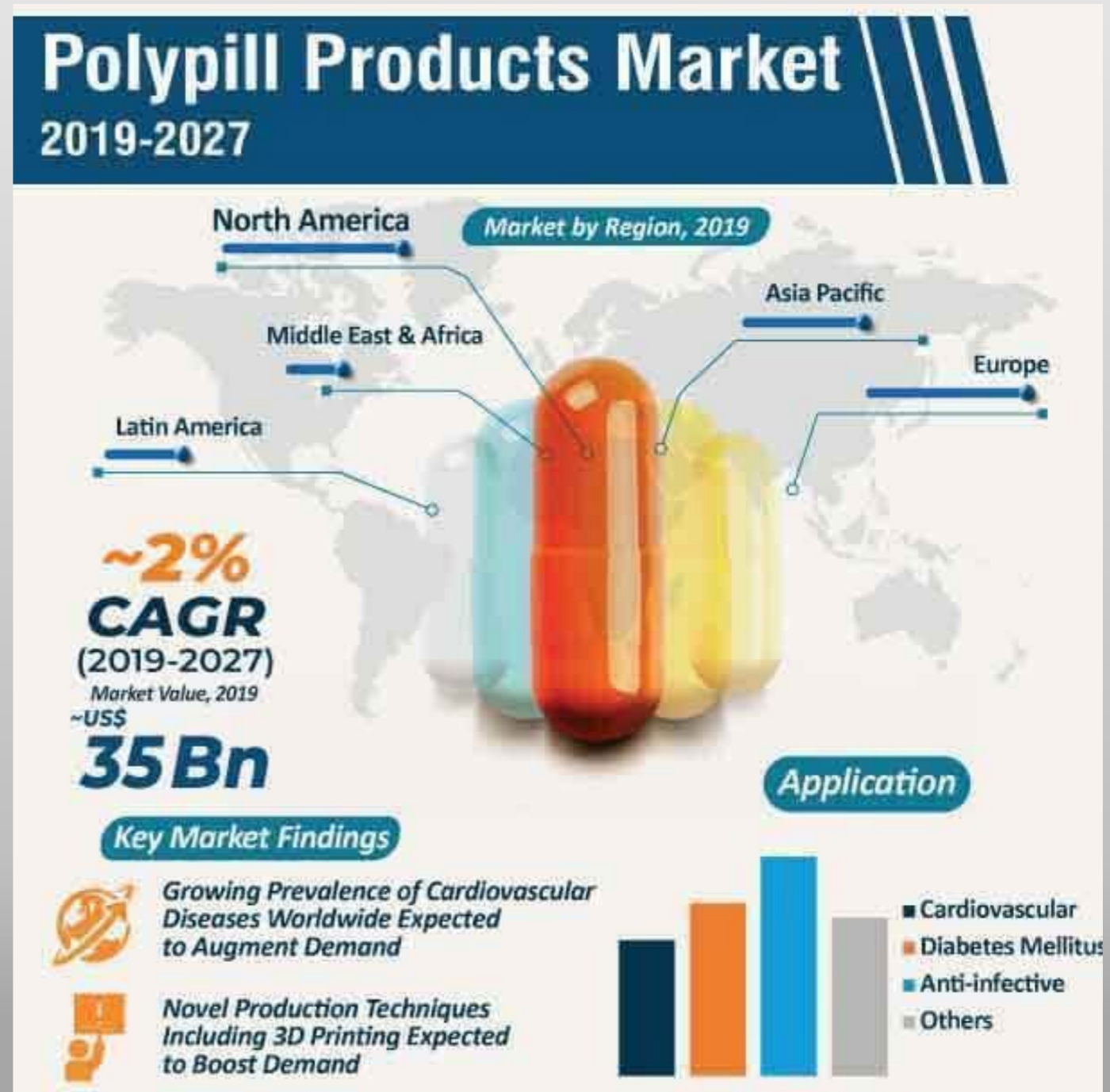


\*Patent Pending US 18/441,356, International PCT 63/484,936

# Personalized Polypill has Global Potential

Market Drivers for Precision PolyPill Solutions affect Every Country

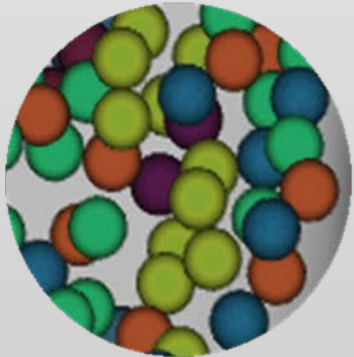
Total Global cardio-metabolic disease market size was valued at \$115 billion - 2023



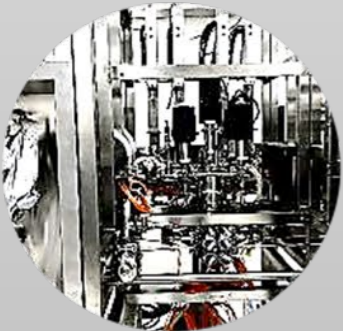
# OneFul Advantages: IP, Regulatory, Experience



## Innovations



### Suspensions



### Robotics



### Data Translation



## Patents

- 13 Patents granted Worldwide including Methods, Computing Device, Systems and Apparatus for Making Customized Formulations
- 6 Patents pending for Drug Suspensions, Personalized Bar Technology, Dosing
- Extensive library of trade secrets includes formulations, processes

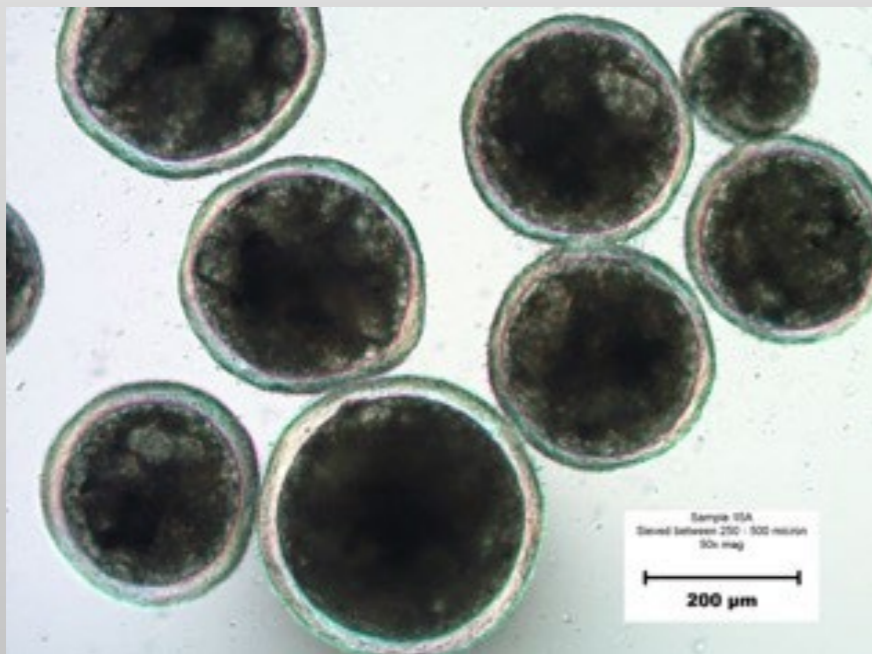


## Regulatory

- 503A License in 10 States
- Operated as 503B FDA Out-Sourcing Facility under full cGMP guidelines
- Novel process for making matrix of drug combinations under USP 795 / 800
- Senior Leadership has 30+ years in regulatory science, clinical trials, and FDA real world practice

# Multi-drug Suspension IP:

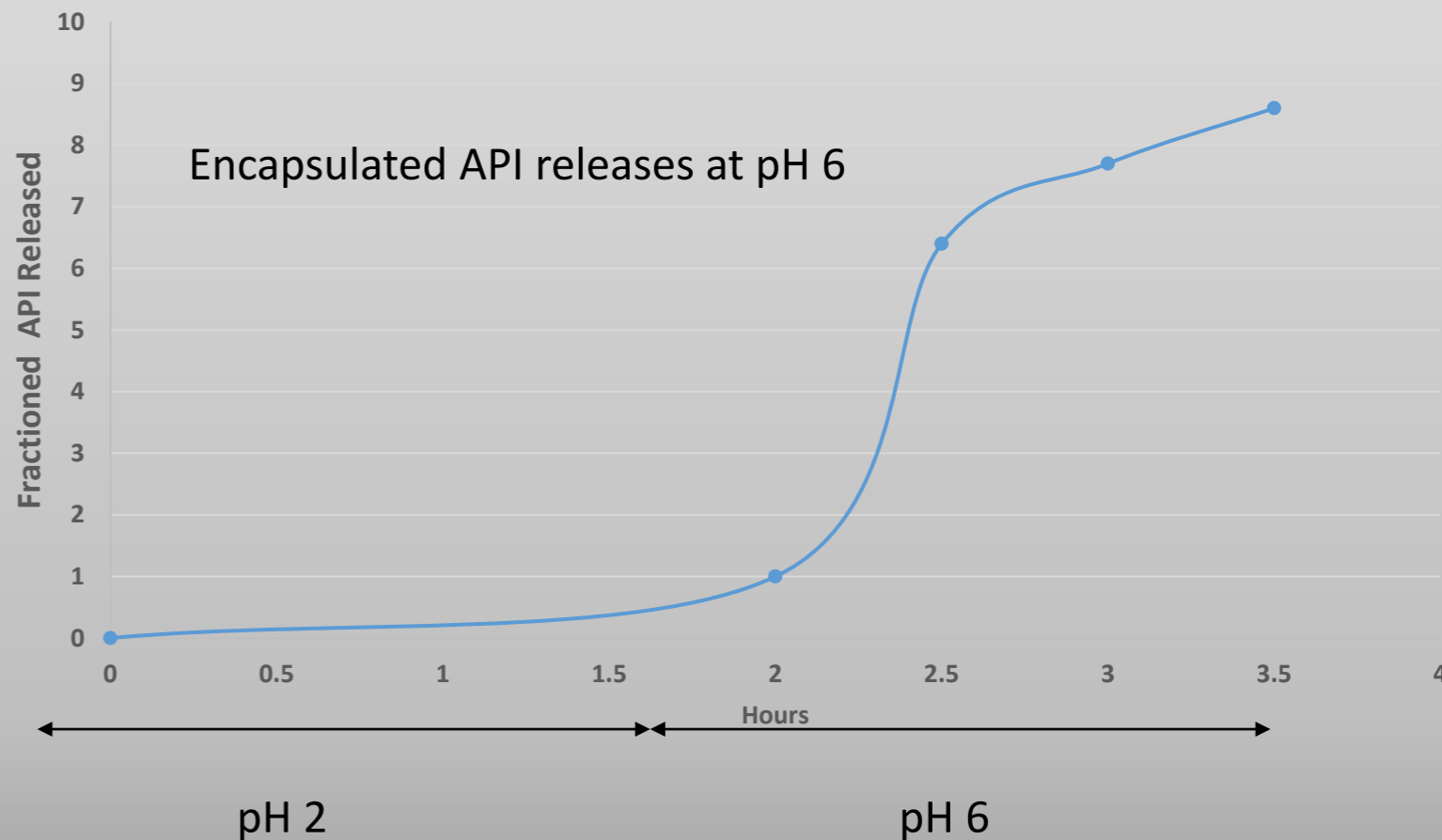
Unique Delivery Forms for High Dosages API Delivery to Specific Regions of Digestive Track. Enables the non-interacting delivery of up to 12-15 active ingredients in 50 g packet



Patent Pending "Suspensions Of Encapsulated Pharmaceuticals And Methods Of Making And Using The Same", (US Patent Application 62/567,779)

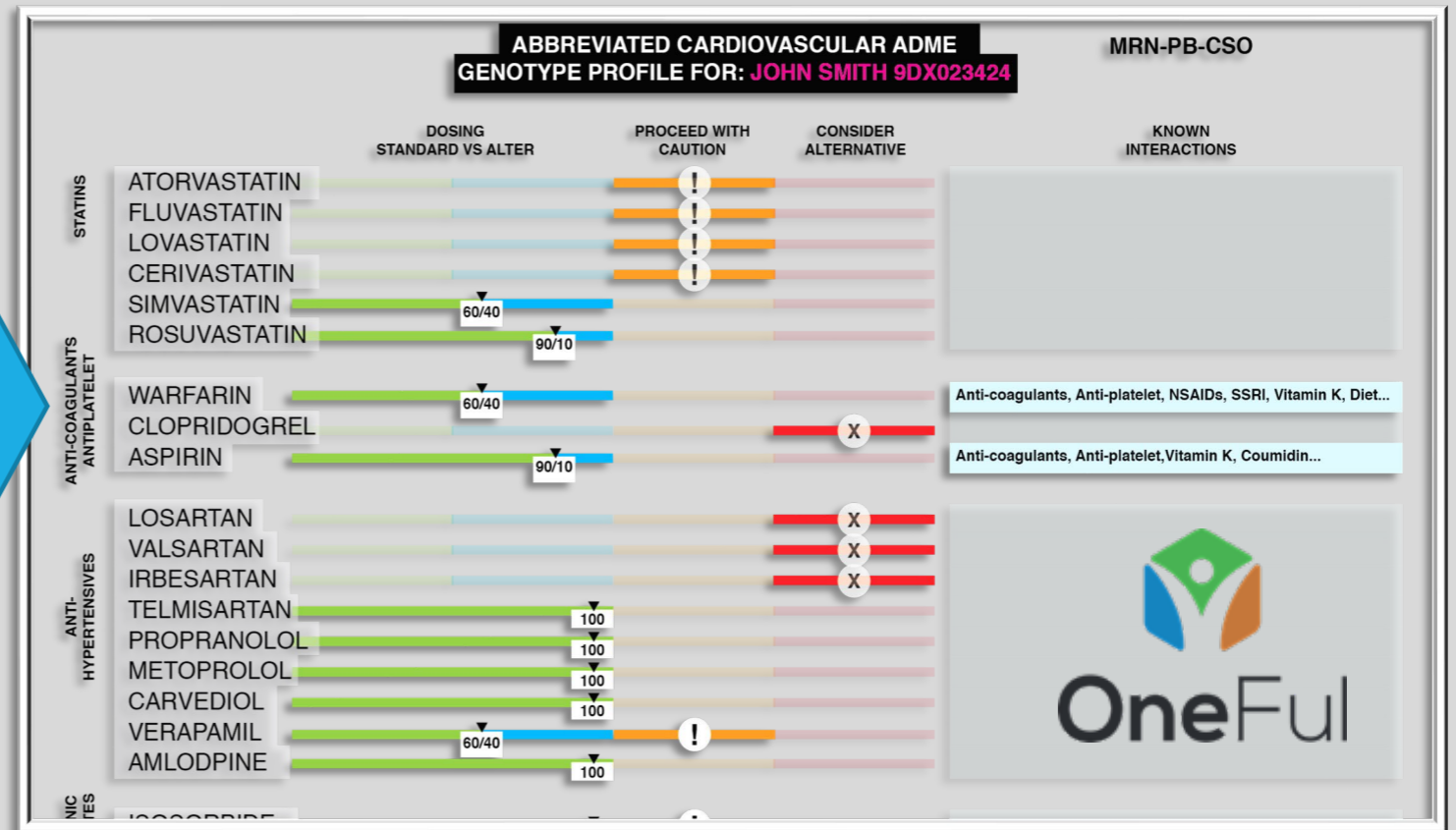
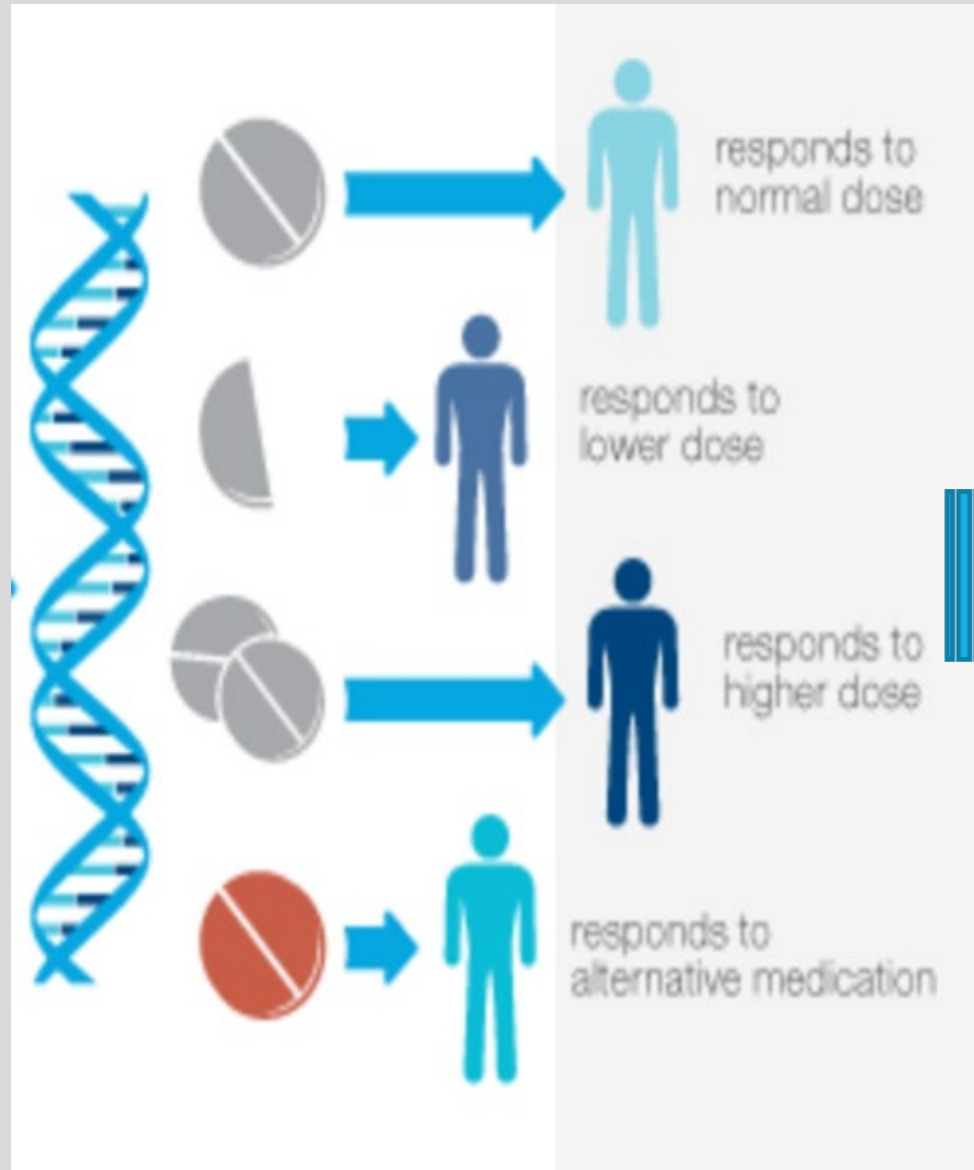


Dissolution of Sample 19  
USP 724 Apparatus II



# Better than PolyPill: Precision Polypill for “N of 1”

Pharmacogenomic Algorithms Licensed from Mayo Clinic Spin-out Geneticure Predicts Optimal Individual CVD Formulation



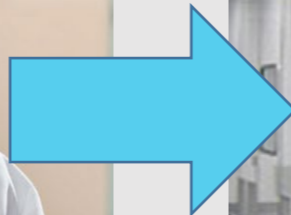
Right Drug, Right Doses for “N of 1”



# Gen 2 Production Proven Volume Platform: Capable of Multi-Drug and Medical Food Suspension Products



# Next Gen Design High Volume Compounding Platform: Multi-Drug or Medical Food Suspension Products – (Gen 3)



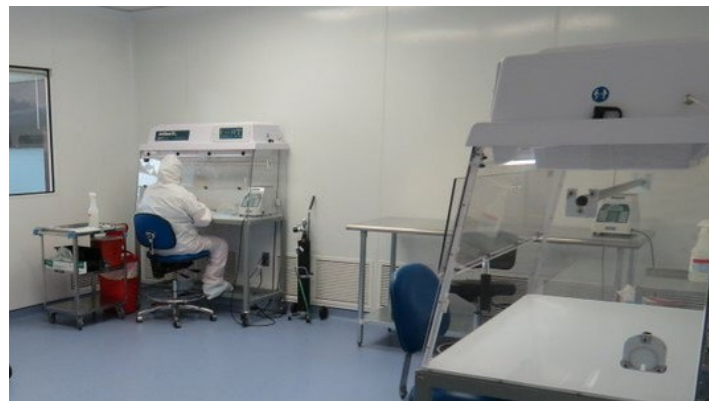
# Commercial and Regulatory Readiness:

## In House Pharma Production Facility



## Accredited Facility

- Triangle Compounding Pharmacy, Cary, NC, (100% owned sub)
- First 503B registered in NC
- ISO 8, ISO 7 suites ISO 5 hoods
- Negative pressure suite
- Certified Blenders, digitally integrated weighing, logging
- Negative pressure ISO 8 suites
- PK Compounder Rx software used to receive, schedule, track prescriptions



# Future Poly-Therapies: Not Just Cardiovascular

AI search of datasets is now discovering precision chronic treatments drug combinations for:

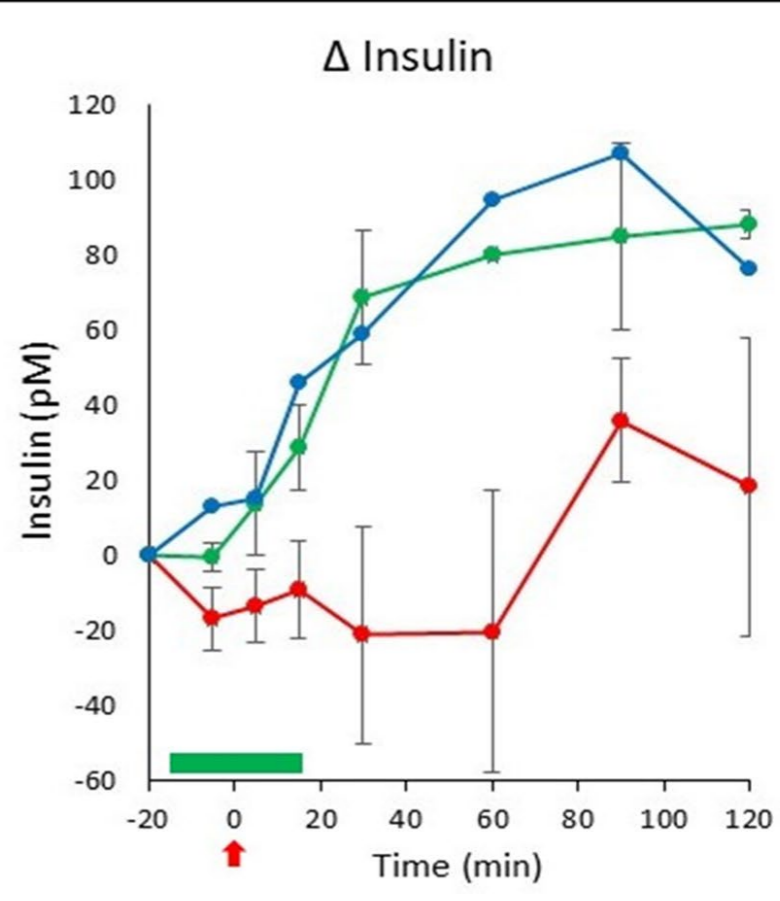
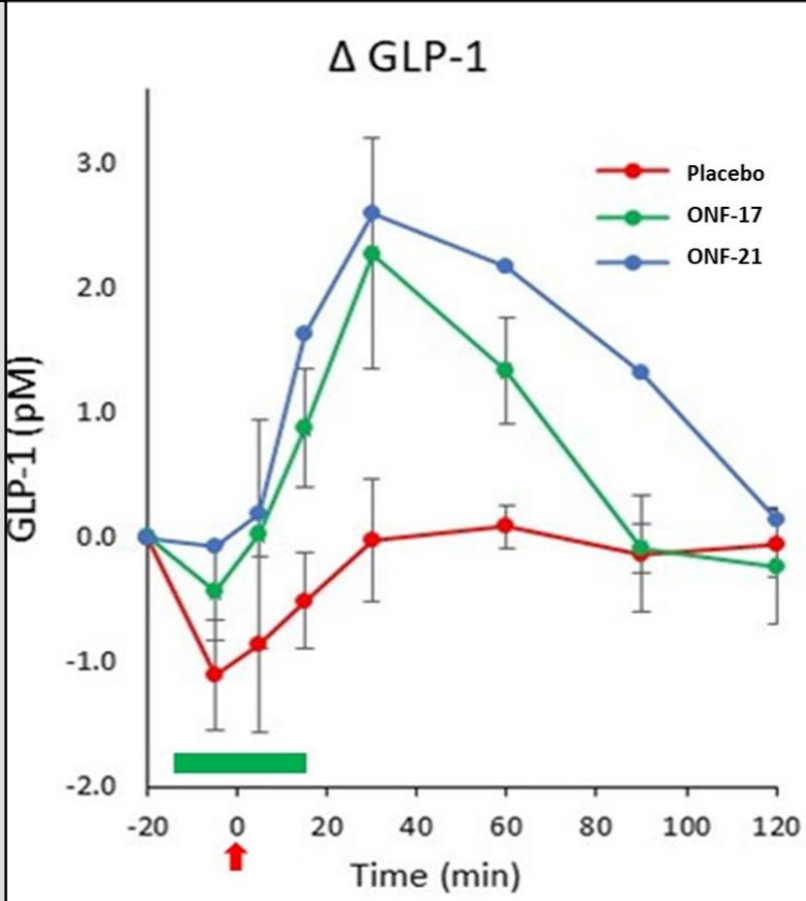
- Metabolic Health
- Mental Health
- New HIV-ART combinations
- Tuberculosis, Malaria combos
- Alzheimer's Disease, Dementias
- Prostate, Others



OneFul Is a “Picks & Shovels” approach to  
Quickly Translate AI-based Discoveries to Clinical Uses

# GLP-OneFul™ Concept Product Development:

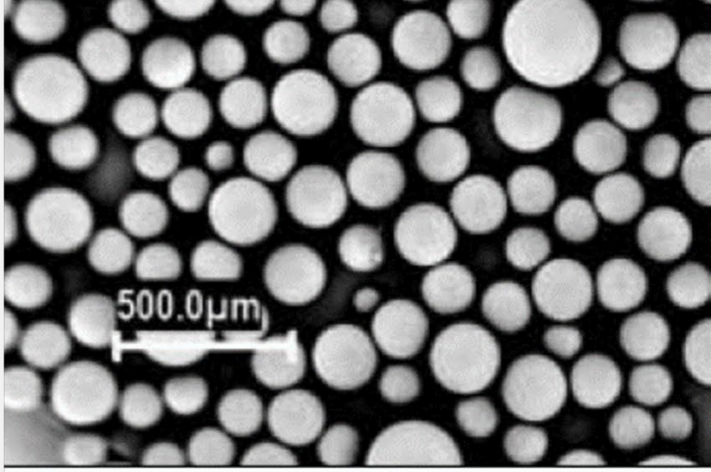
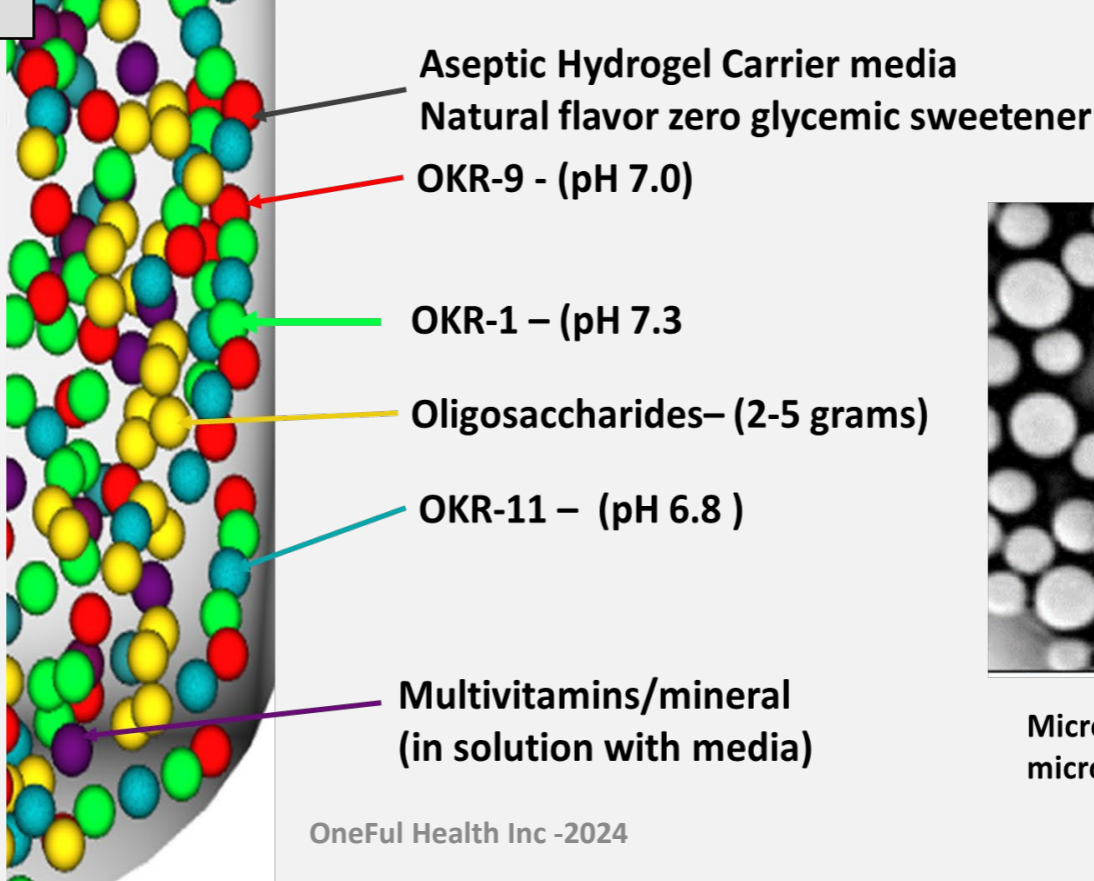
- Endogenous GLP-1 agonists
- Micro-encapsulated actives
- Oligosaccharides for microbiota
- Nutrients for general nutrition
- Minimal adverse side effects
- Post-semaglutide/terzepatide weight loss/ diabetes maintenance
- Obesity therapy in children potential first application



Active Ingredients micro-encapsulated and coated for sustained GLP-1, PYY release in distal colon for 8 to 12 hours



50-gram squeeze pouch, shelf stable, flavored



Microcapsules average diameter of 700 microns, 30-35% API loading

# Partnership Agreements:

Telemedicine, Concierge Physician networks and Testing partners



Discussions with several hospital systems indicates future potential:



[\\*See Advent Health Made Video about OneFul \(formerly Panaceutics\)](#)

# Partnerships in Discussion\*: To Bring National Sales / distribution

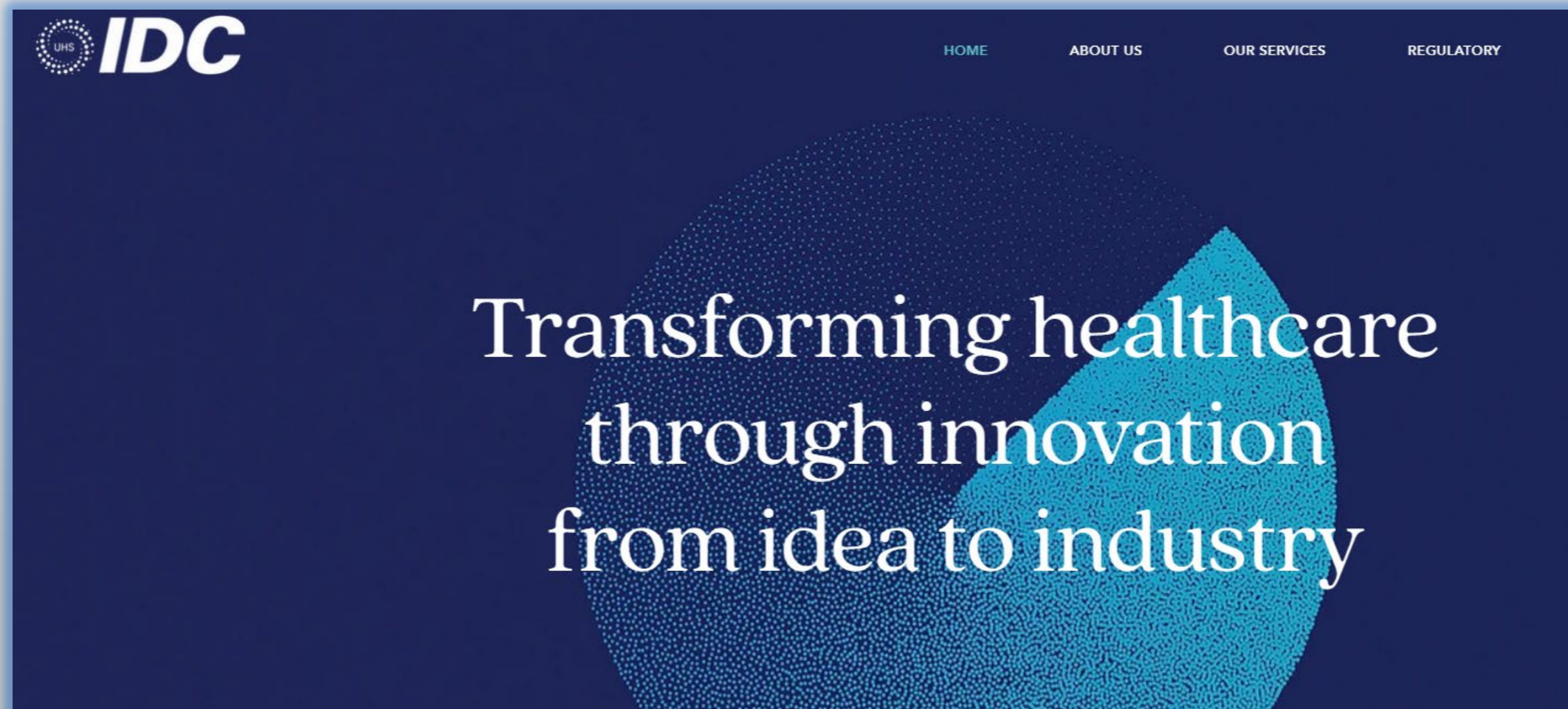


\*National 503A network distribution agreement expected to close Q3 2024

# Global Partners and Licensing:

## UK Partners: ID-Health/Avida Medical

- UK NHS-Innovation funded tech transfer and pilot
- 500 person CVD polypill pilot at Southampton Hospital in 2025



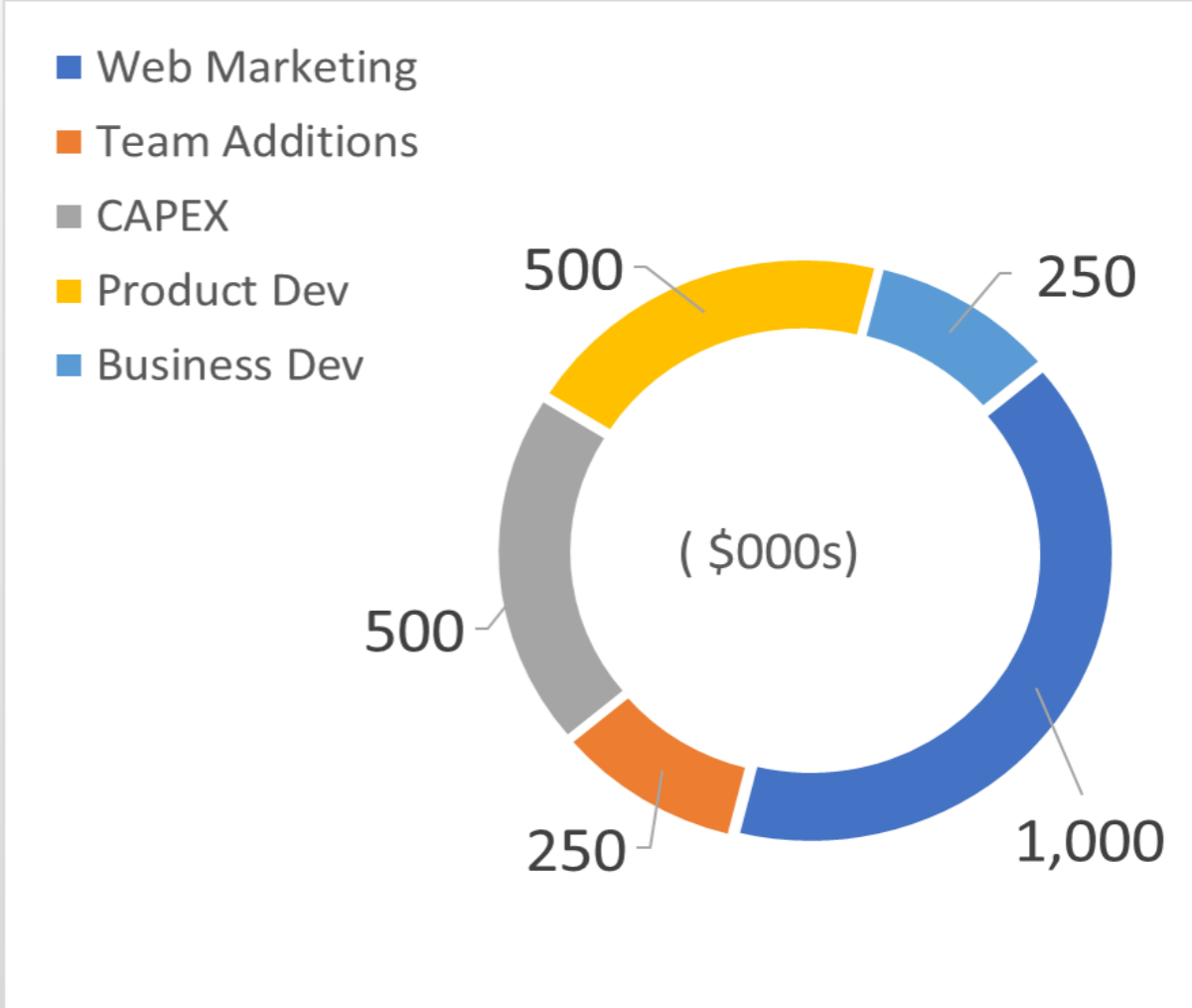


# Investment Goals

**Funds Raised to Date: \$7.1 M**

**Venture / Strategic – Q3 2024:**  
**Series A Preferred Shares**  
**\$5,000,000.**

**Supporting capacity additions and new product development and trials**



**Projected Use of Funds  
Q1 2024 thru Q1 2025**

# Proven Leadership Team and Advisors



**Edison Hudson**  
CEO / CTO

- Former iRobot Exec
- Automation & AI Expert
- 20+ Patents
- 7 startups, 4 Exits
- 2 IPO teams
- Director Panaceutics Nutrition Inc
- Duke MBA, Oxford AI



**Danny Barnes, RPh**  
PharmD, Chief Pharmacy Officer

- Founder Triangle Compounding Rx
- 20+ yrs in compounding pharmacy
- First NC registered 503B FDA Outsourcing Facility
- IACP Board Member



**Garrett Ruhland**  
Chief Digital Marketing Officer / CIO

- BioMarker Labs, CEO Founder
- Digital healthcare marketing expert in Bay Area
- Hedge fund Advisor, Koroit Capital
- Biochemistry, molecular biology, Duke Univ
- UCL London studies



**Arthur Kellermann, MD, MPH**  
Chief Medical Officer

- Healthcare leader, expertise in academic medicine, emergency care, public health, military medicine and health policy
- CEO of VCU Health System, Dean, School of Medicine, Uniformed Services University
- Paul O'Neill/Alcoa Chair in Policy Analysis at the RAND Corporation
- Forbes Contributor



**Eva Doss**  
Board Member

- CEO -The Launch Place venture fund
- 25 yrs in business consulting, strategic planning, equity
- Secured \$50 million in private equity
- Booz Allen, Research Triangle Institute, USAID Executive
- MIT Sloan School



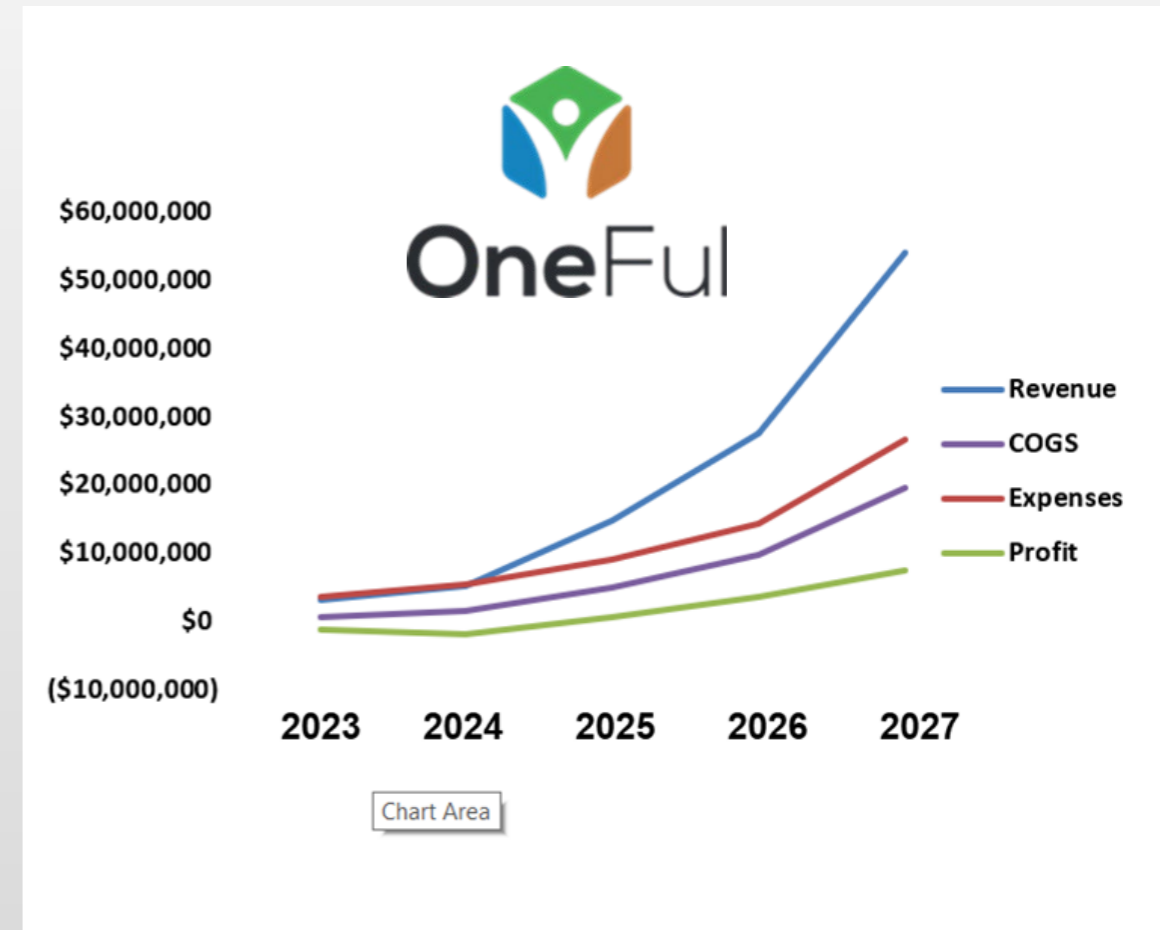
**Deon Joubert**  
Board Chairman

- Represents Sanitarium Health & Wellbeing (AUS)
- Executive General Manager
- Sanitarium is one of Australia/New Zealand's largest health food companies, and operates major hospitals
- Responsibility for a range of treasury and finance functions, banking, insurance, legal and M&A.,
- Reports to the Chief Executive Officer



# Why Invest?

- ✓ Individualized treatments that work better for patients, high adherence and fewer adverse effects.
  - ✓ Improves the quality of life for millions with chronic illness.
  - ✓ Over 100,000 Preventable deaths/ year in USA from non-adherence alone.
- 
- ✓ 13+ patents issued in personalized medicine, digital health, proven automation systems
  - ✓ The precision CVD-P<sup>3</sup> product meets all regulatory, quality milestones, patients love it
  - ✓ Proven management, accredited facilities, national expansion plan results in \$1B potential



Edison Hudson | [edison@oneful.health](mailto:edison@oneful.health) | (919) 215-9358 | [www.oneful.health](http://www.oneful.health)



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***Making Medicines  
Work Better For EveryONE***

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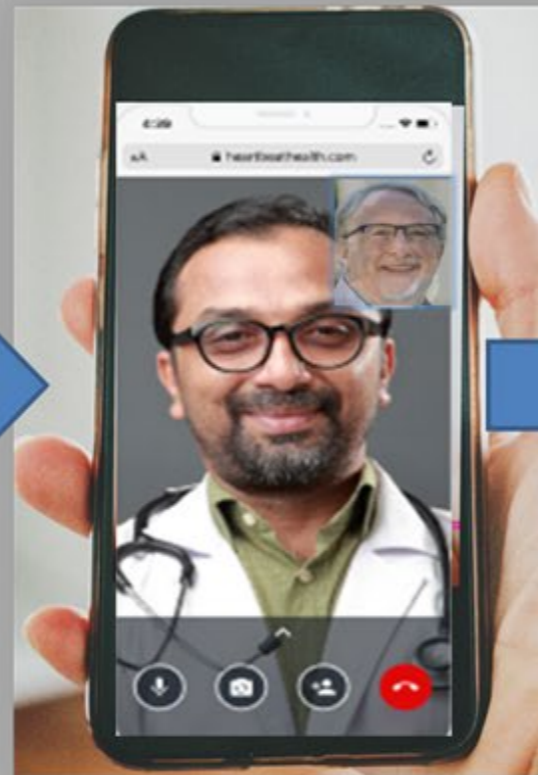
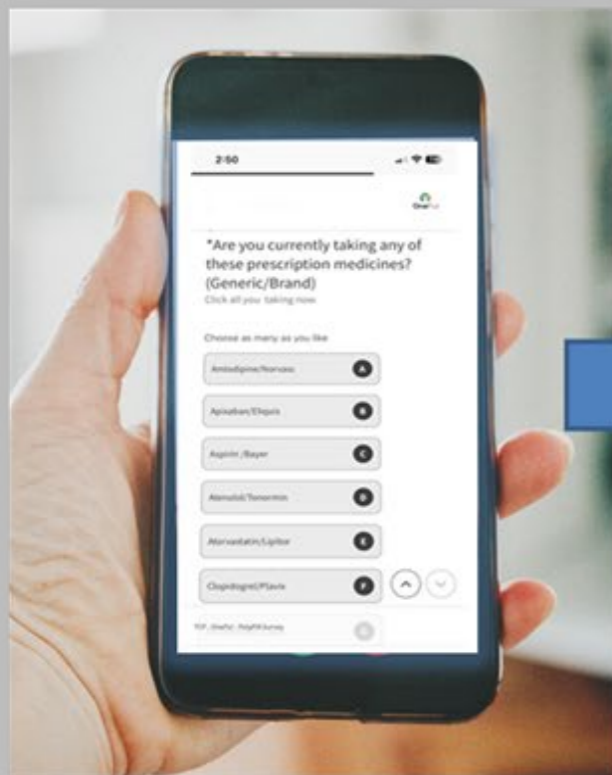
Research Triangle Park  
North Carolina 27709 USA



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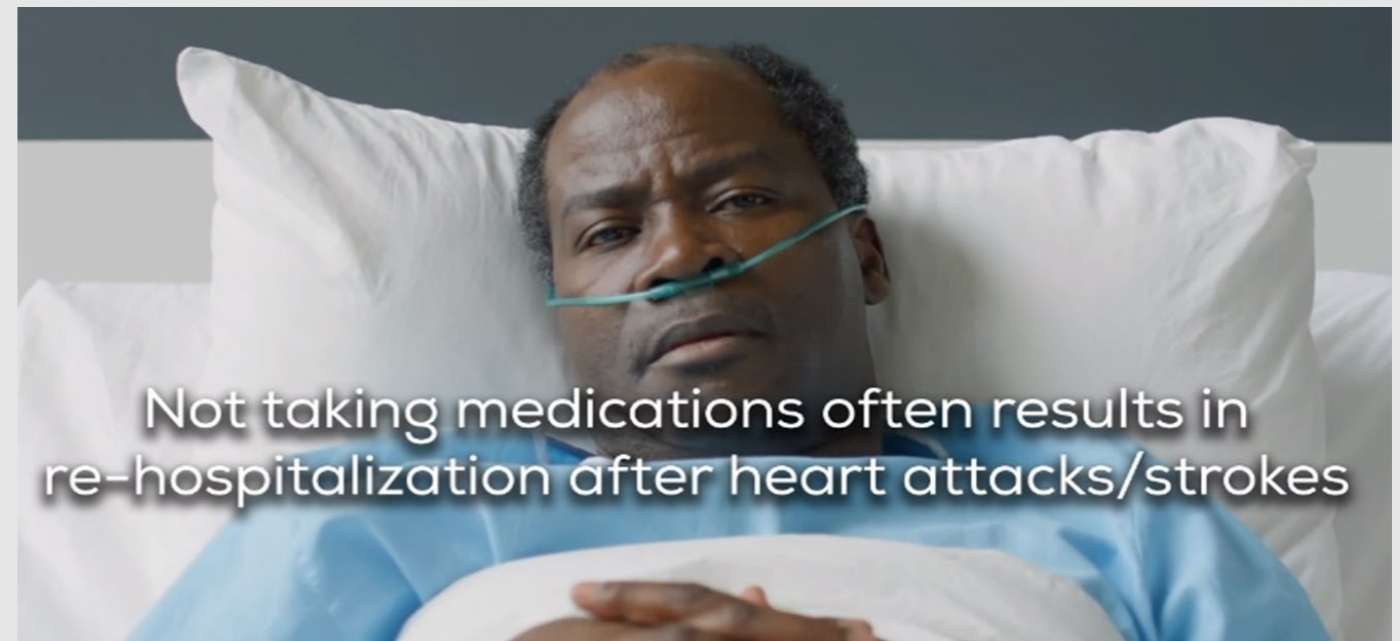
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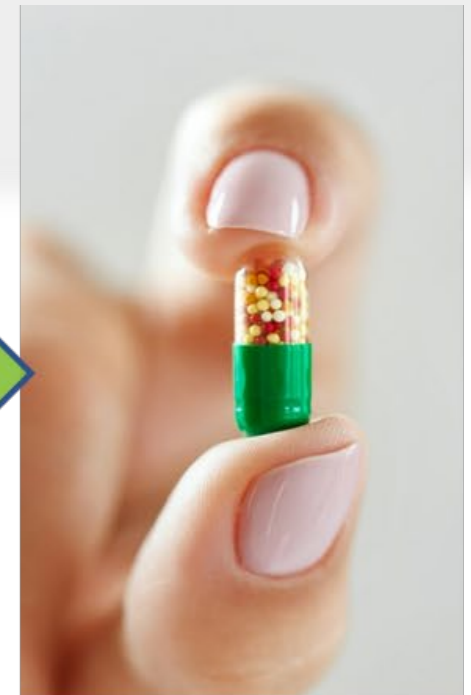
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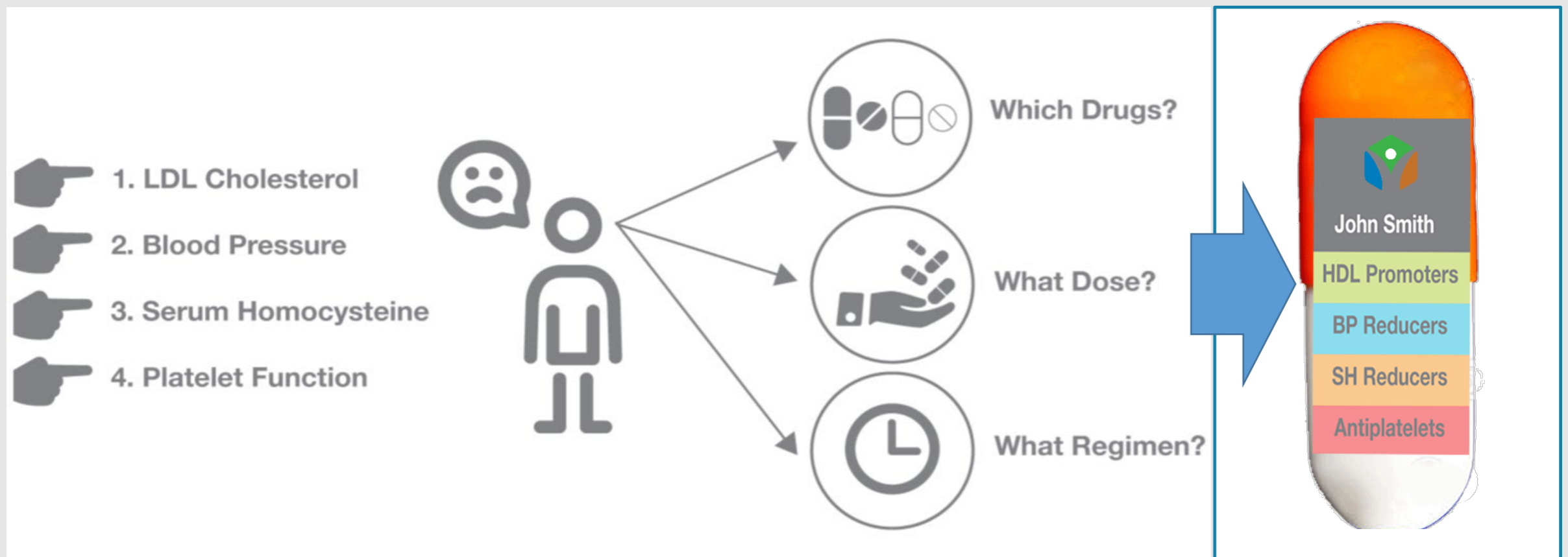
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**CVD-P<sup>3</sup>**

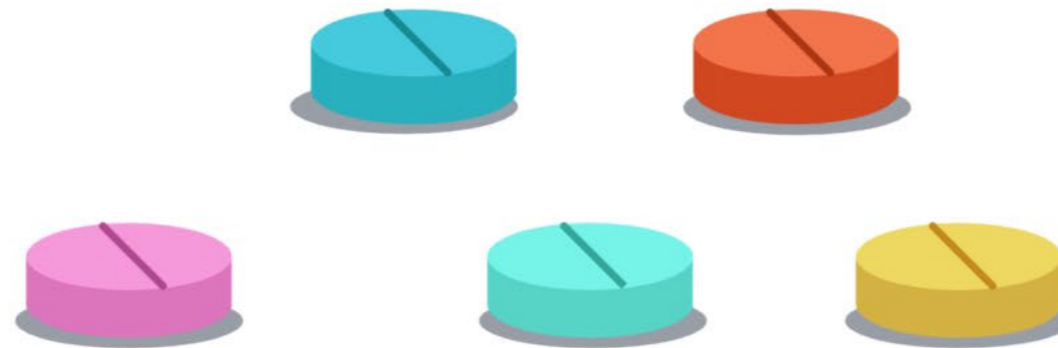


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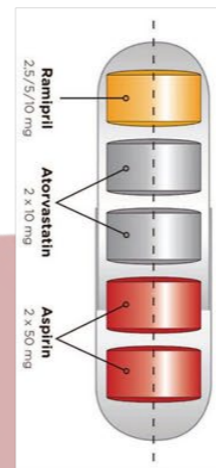


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ramipril	ACE inhibitor	2.5mg / 5mg / 10mg		5				2.5/5/10
losartan	ARB	25mg / 50mg	25		25/50			
aspirin	Anti -Platelet	81mg / 100 mg		100		81	81	
clopidogrel	Anti -Platelet	75mg			100	75	75	
metoprolol	Beta Blocker	25mg / 50mg /100 mg				25/50/100	25/50/100	
atenolol	Beta Blocker	25mg / 50mg /100 mg						25/50/100
amlodipine	Calcium-C blocker	2.5mg / 5mg	2.5					
hydrochlorothiazide (HCTZ)	Diuretic /Anti Edemic	12.5 mg / 25mg	12.5	12.5				12.5/25
atorvastatin	Statin	10mg / 20mg / 40mg		20/40	20/40		10/20/40	
rosuvastatin	Statin	10mg / 20mg / 40mg	10			10/20/40		
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- 1,800 multi-API polypills / hour
- Automated bulk capsule load/open/close/eject
- Rapid changeover API cartridges
- Minimized cleaning
- Negative Pressure enclosure
- Two fillers controlled from single supervisory console



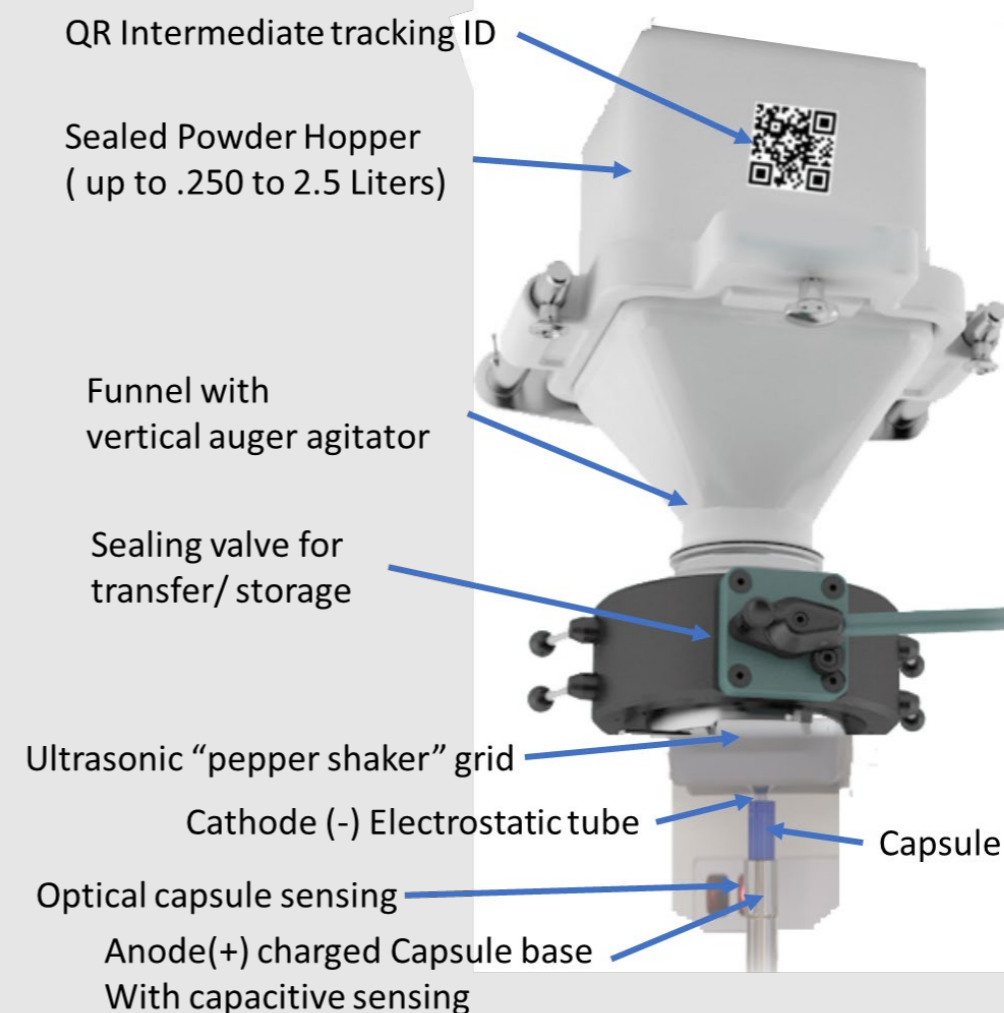
**Low CAPEX, small footprint systems  
yields RoI less than 6 month**

# Key Innovation:

## Digital Micro-dosing Electrodynamic Cartridge 'DMEC'\*

### Digital Drug 'toner cartridge'

- Up to five DMEC dosing heads per filler
- 5-7 APIs onboard concurrently
- Dosing accuracy to 0.1 milligram
- 150 mg/sec powder dispense (v1.0)
- Closed loop dosage measure & logging
- API validation and tracking via block-chain linked QR coding
- CE certification, cGMP SoPs, IQ/OQ documentation



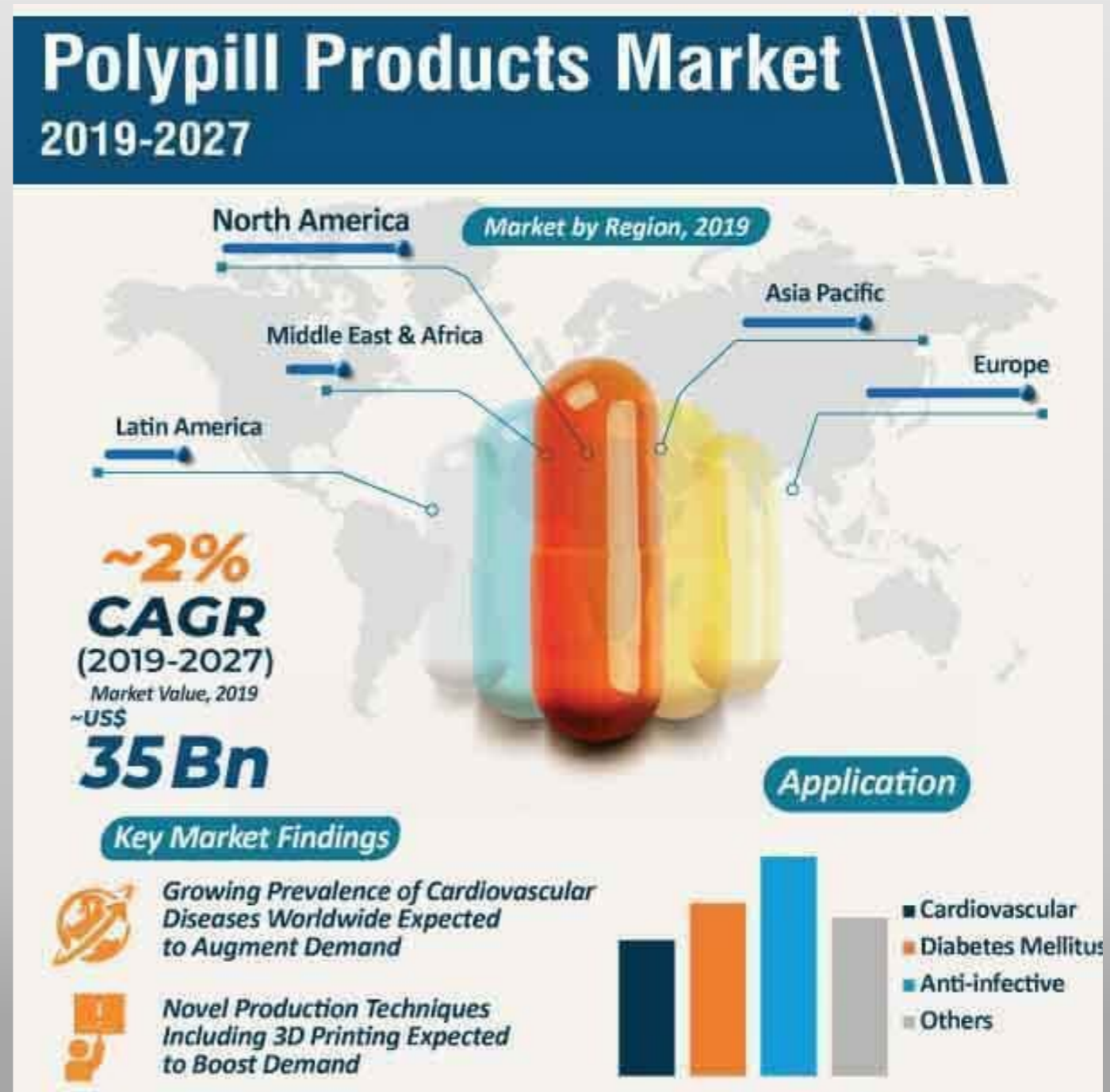
\*Patent Pending US 18/441,356, International PCT 63/484,936



# Personalized Polypill has Global Potential

Market Drivers for Precision PolyPill Solutions affect Every Country

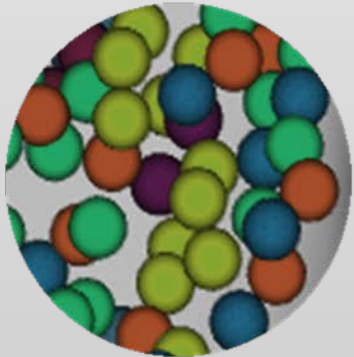
Total Global cardio-metabolic disease market size was valued at \$115 billion - 2023



# OneFul Advantages: IP, Regulatory, Experience



## Innovations



### Suspensions



### Robotics



### Data Translation



## Patents

- 13 Patents granted Worldwide including Methods, Computing Device, Systems and Apparatus for Making Customized Formulations
- 6 Patents pending for Drug Suspensions, Personalized Bar Technology, Dosing
- Extensive library of trade secrets includes formulations, processes

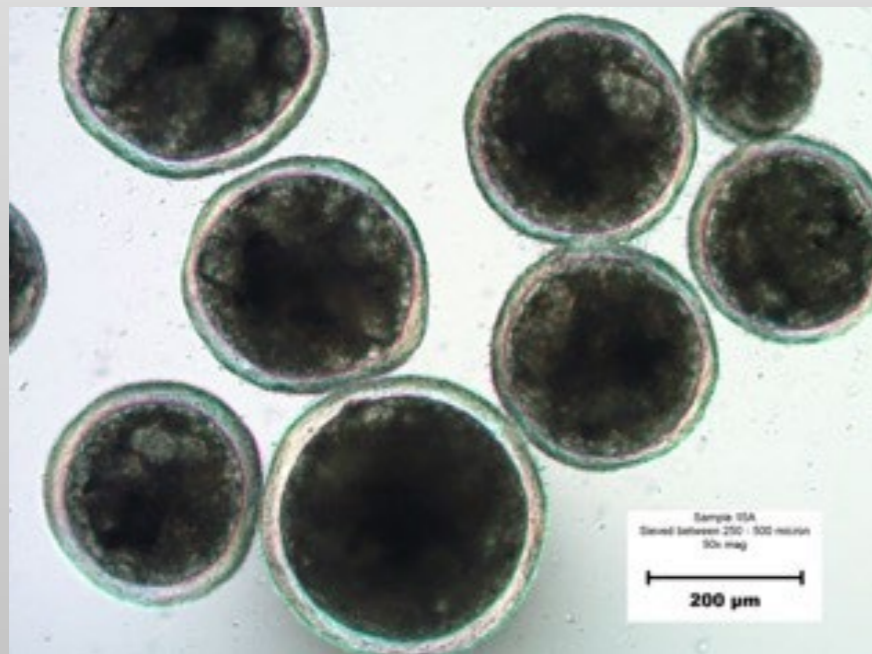


## Regulatory

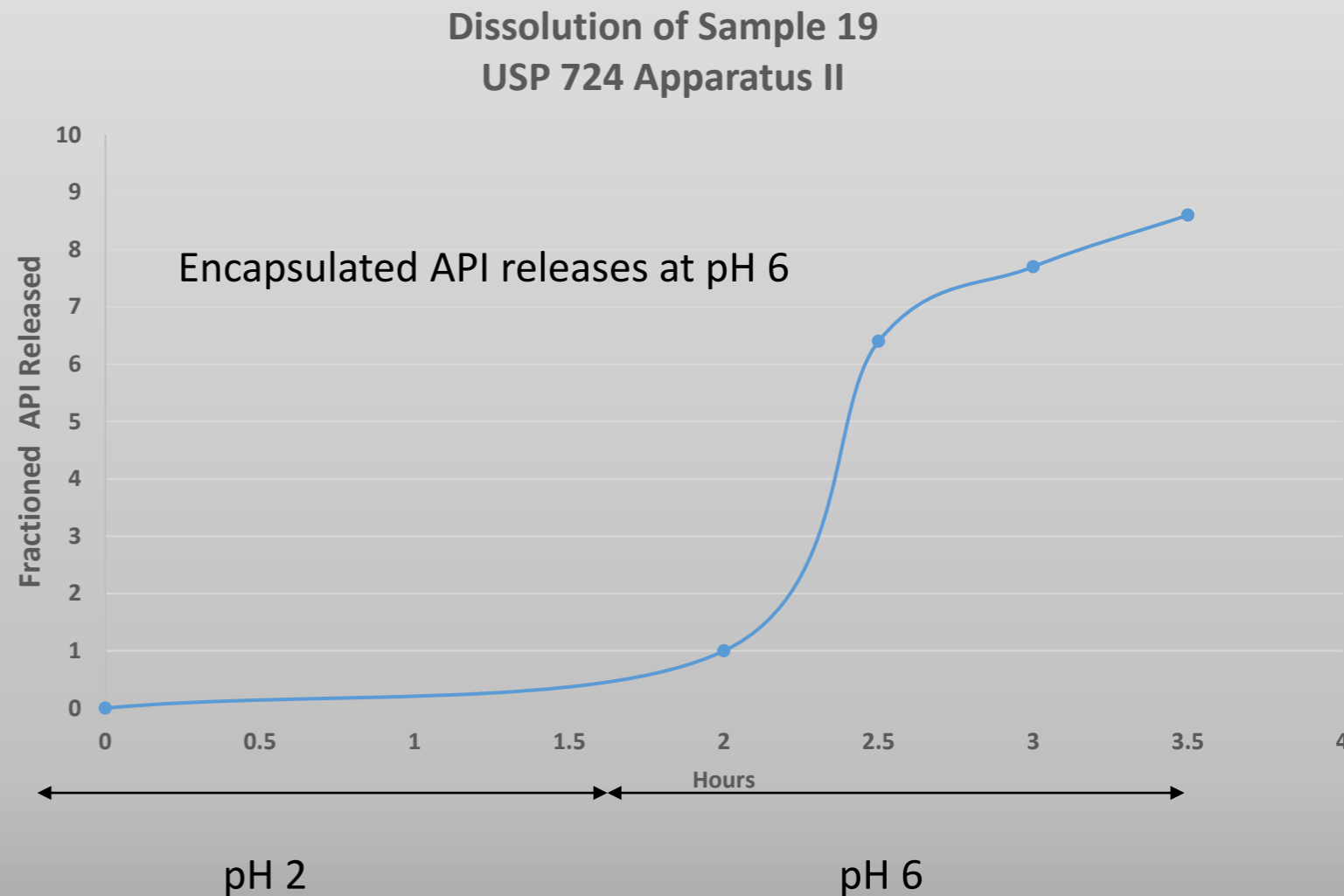
- 503A License in 10 States
- Operated as 503B FDA Out-Sourcing Facility under full cGMP guidelines
- Novel process for making matrix of drug combinations under USP 795 / 800
- Senior Leadership has 30+ years in regulatory science, clinical trials, and FDA real world practice

# Multi-drug Suspension IP:

Unique Delivery Forms for High Dosages API Delivery to Specific Regions of Digestive Track. Enables the non-interacting delivery of up to 12-15 active ingredients in 50 g packet

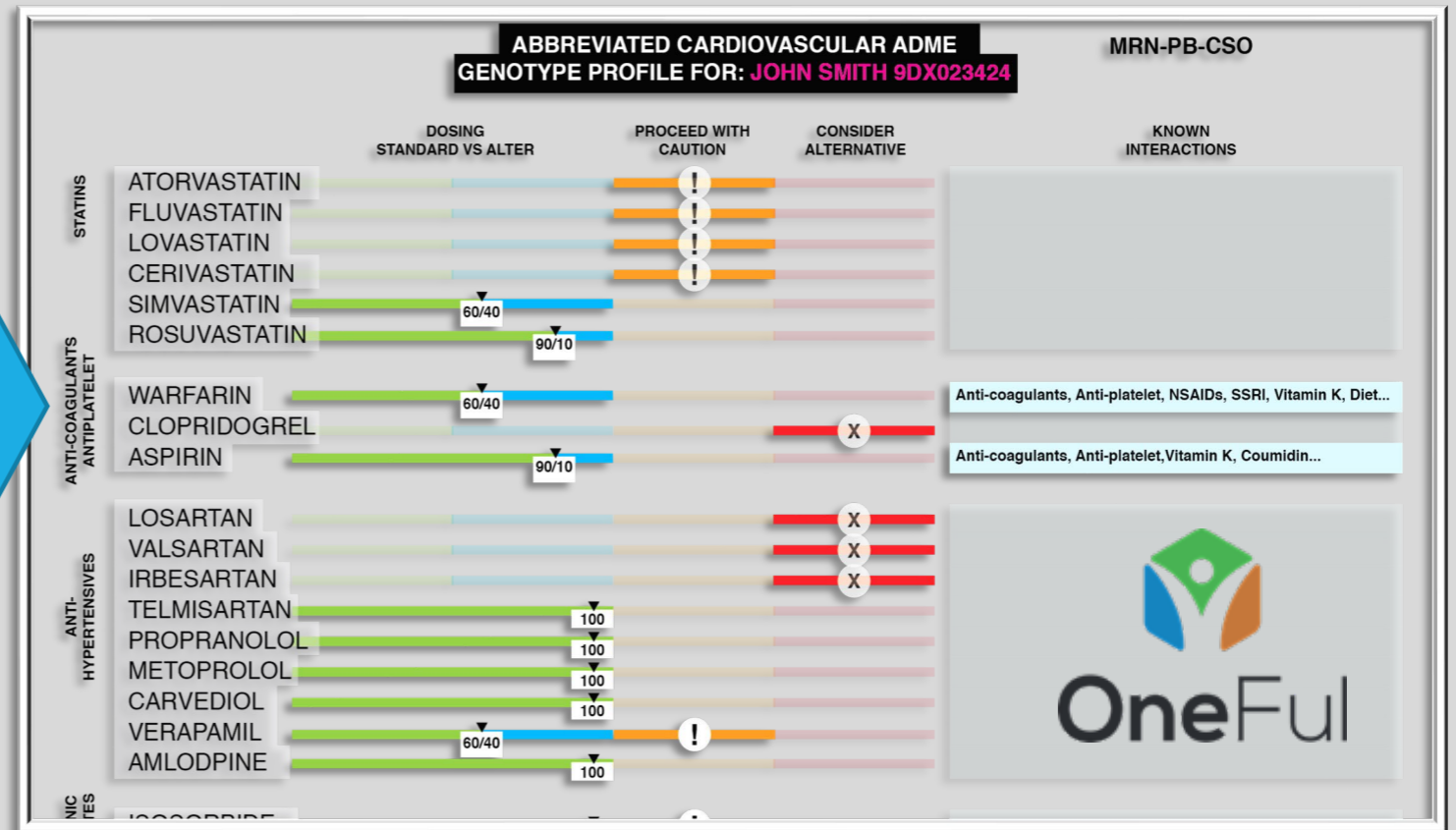
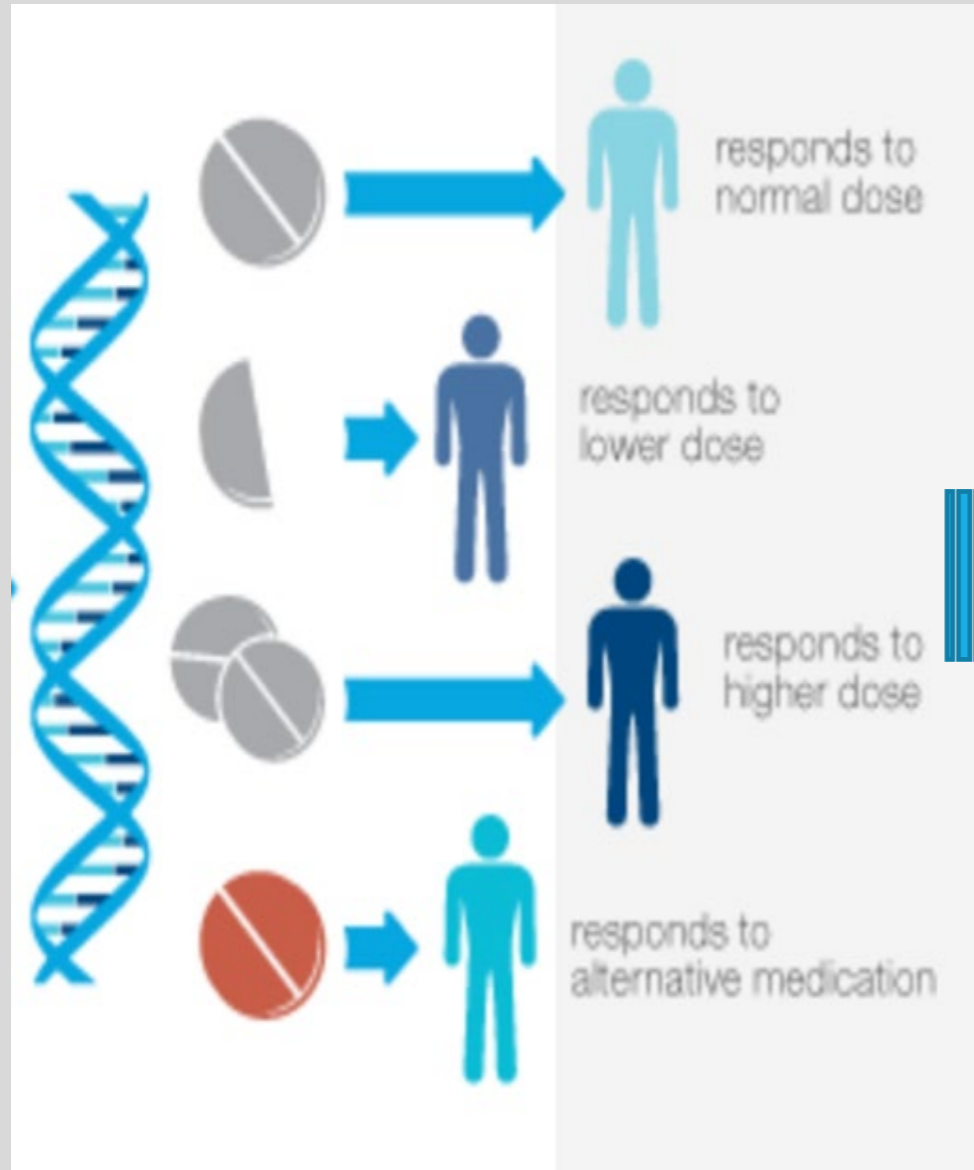


Patent Pending "Suspensions Of Encapsulated Pharmaceuticals And Methods Of Making And Using The Same", (US Patent Application 62/567,779)



# Better than PolyPill: Precision Polypill for “N of 1”

Pharmacogenomic Algorithms Licensed from Mayo Clinic Spin-out Geneticure Predicts Optimal Individual CVD Formulation



Right Drug, Right Doses for “N of 1”

# Gen 2 Production Proven Volume Platform: Capable of Multi-Drug and Medical Food Suspension Products



# Next Gen Design High Volume Compounding Platform: Multi-Drug or Medical Food Suspension Products – (Gen 3)



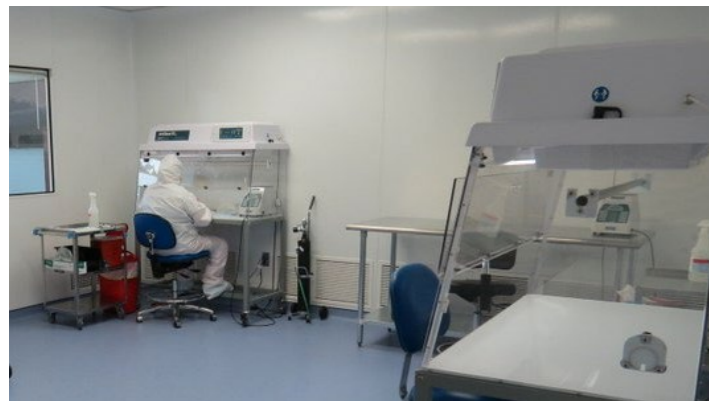
# Commercial and Regulatory Readiness:

## In House Pharma Production Facility



## Accredited Facility

- Triangle Compounding Pharmacy, Cary, NC, (100% owned sub)
- First 503B registered in NC
- ISO 8, ISO 7 suites ISO 5 hoods
- Negative pressure suite
- Certified Blenders, digitally integrated weighing, logging
- Negative pressure ISO 8 suites
- PK Compounder Rx software used to receive, schedule, track prescriptions



# Future Poly-Therapies: Not Just Cardiovascular

AI search of datasets is now discovering precision chronic treatments drug combinations for:

- Metabolic Health
- Mental Health
- New HIV-ART combinations
- Tuberculosis, Malaria combos
- Alzheimer's Disease, Dementias
- Prostate, Others

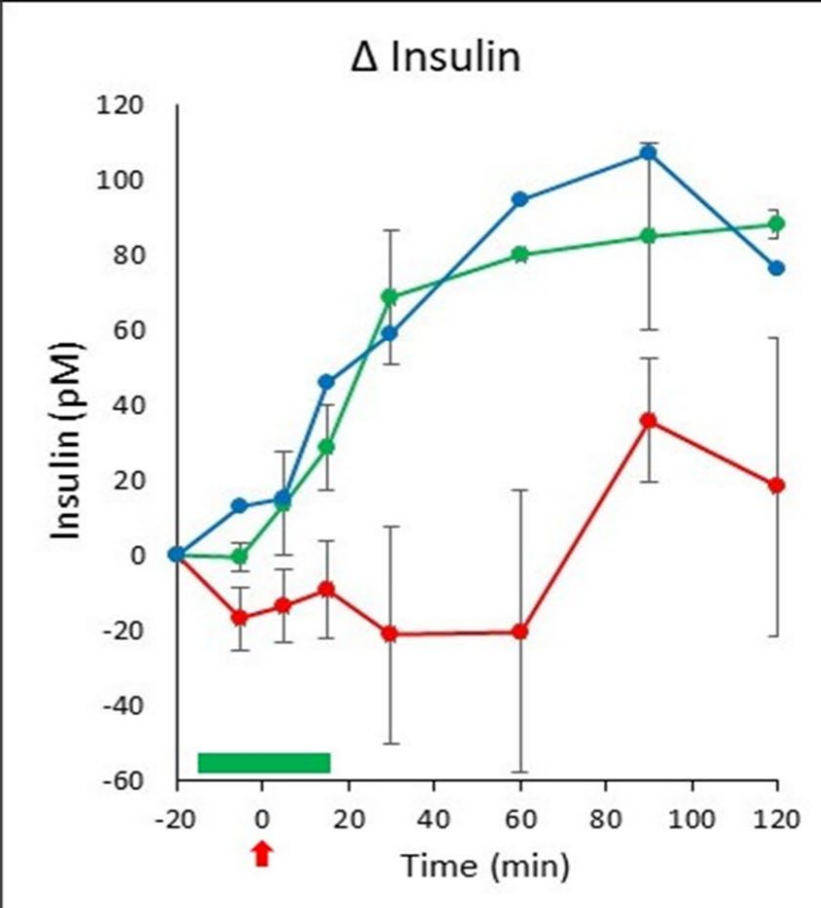
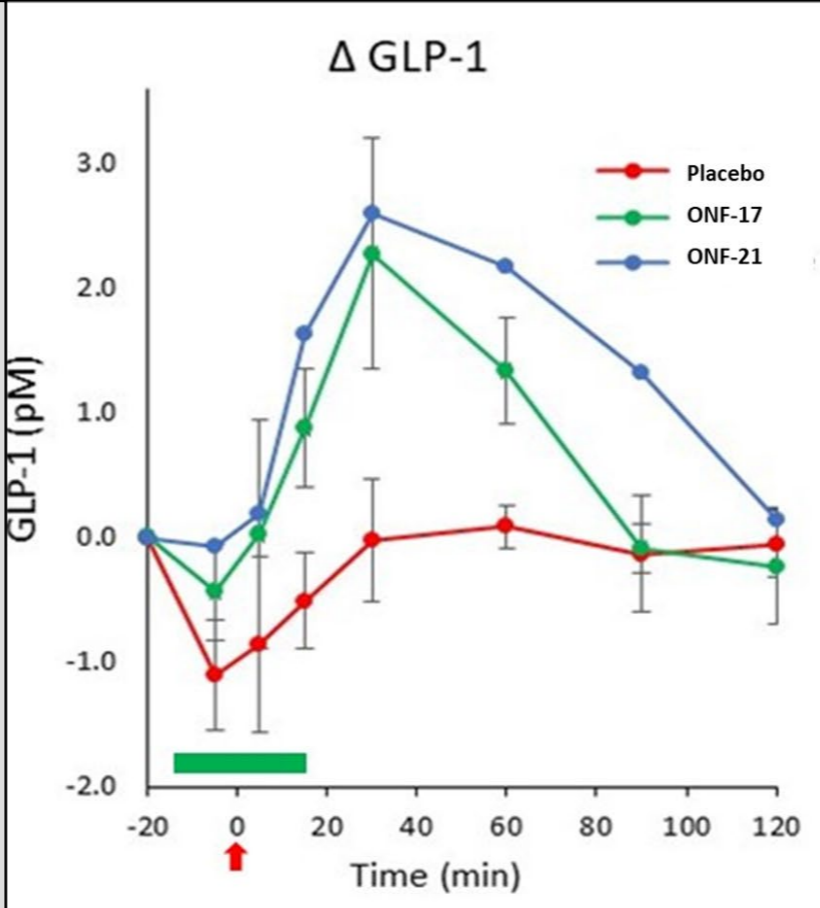


OneFul Is a “Picks & Shovels” approach to  
Quickly Translate AI-based Discoveries to Clinical Uses



# GLP-OneFul™ Concept Product Development:

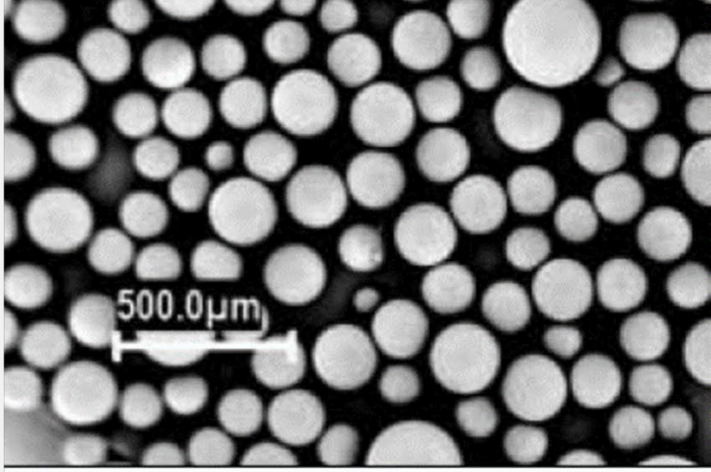
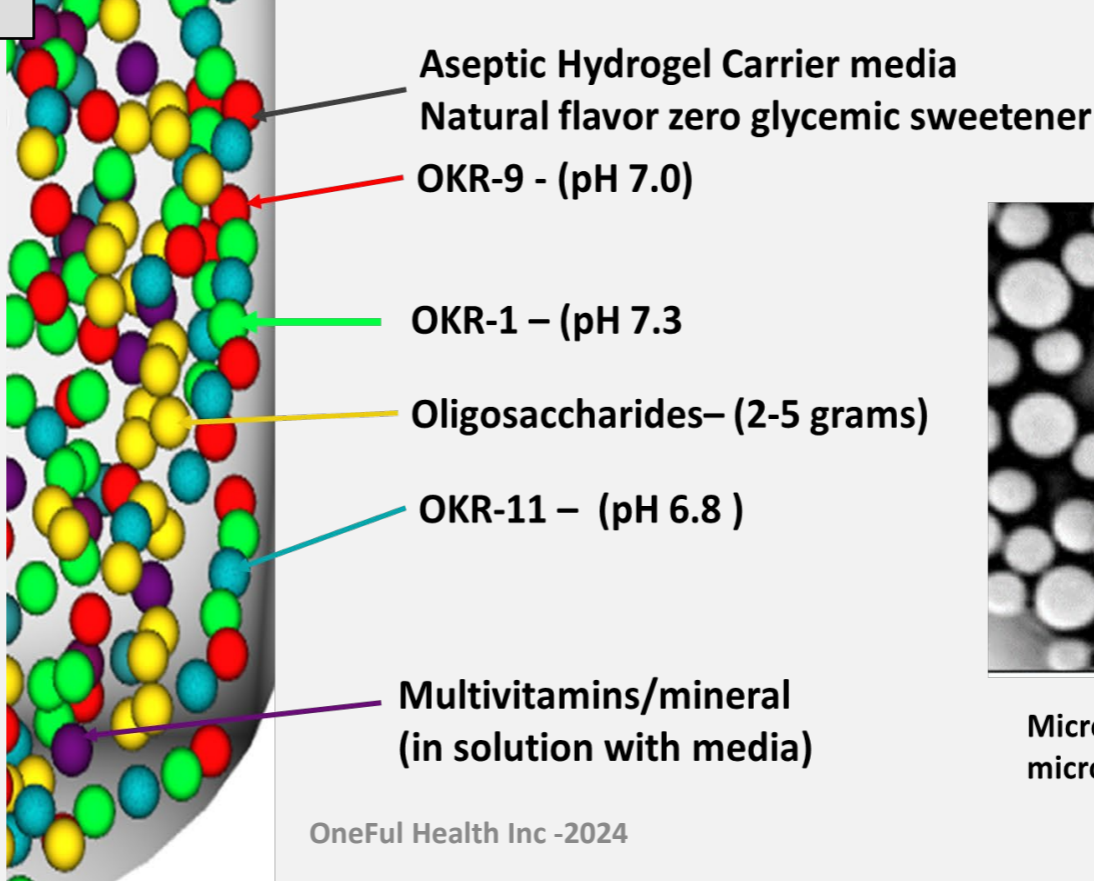
- Endogenous GLP-1 agonists
- Micro-encapsulated actives
- Oligosaccharides for microbiota
- Nutrients for general nutrition
- Minimal adverse side effects
- Post-semaglutide/terzepatide weight loss/ diabetes maintenance
- Obesity therapy in children potential first application



Active Ingredients micro-encapsulated and coated for sustained GLP-1, PYY release in distal colon for 8 to 12 hours



50-gram squeeze pouch, shelf stable, flavored



Microcapsules average diameter of 700 microns, 30-35% API loading

# Partnership Agreements:

Telemedicine, Concierge Physician networks and Testing partners



Discussions with several hospital systems indicates future potential:



[\\*See Advent Health Made Video about OneFul \(formerly Panaceutics\)](#)

# Partnerships in Discussion\*: To Bring National Sales / distribution

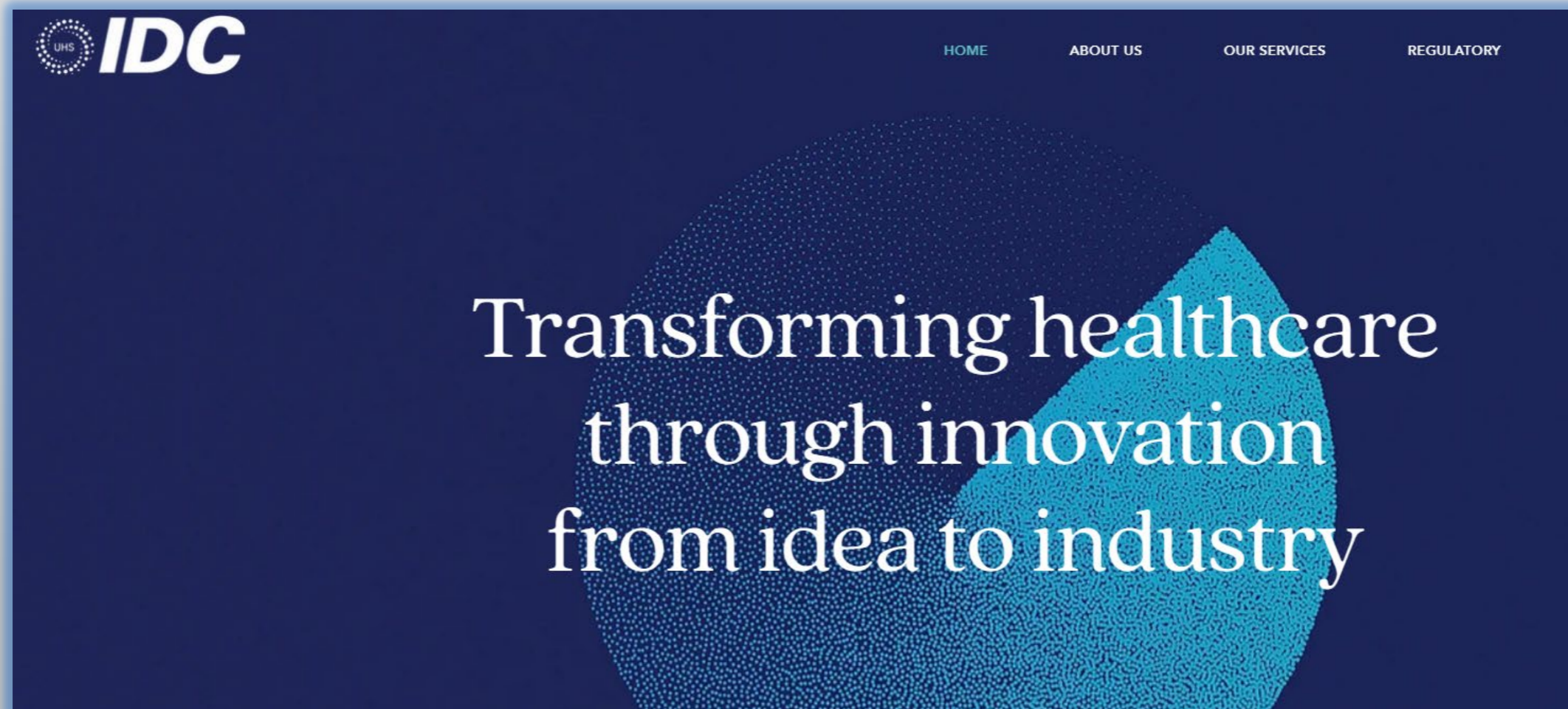


\*National 503A network distribution agreement expected to close Q3 2024

# Global Partners and Licensing:

## UK Partners: ID-Health/Avida Medical

- UK NHS-Innovation funded tech transfer and pilot
- 500 person CVD polypill pilot at Southampton Hospital in 2025

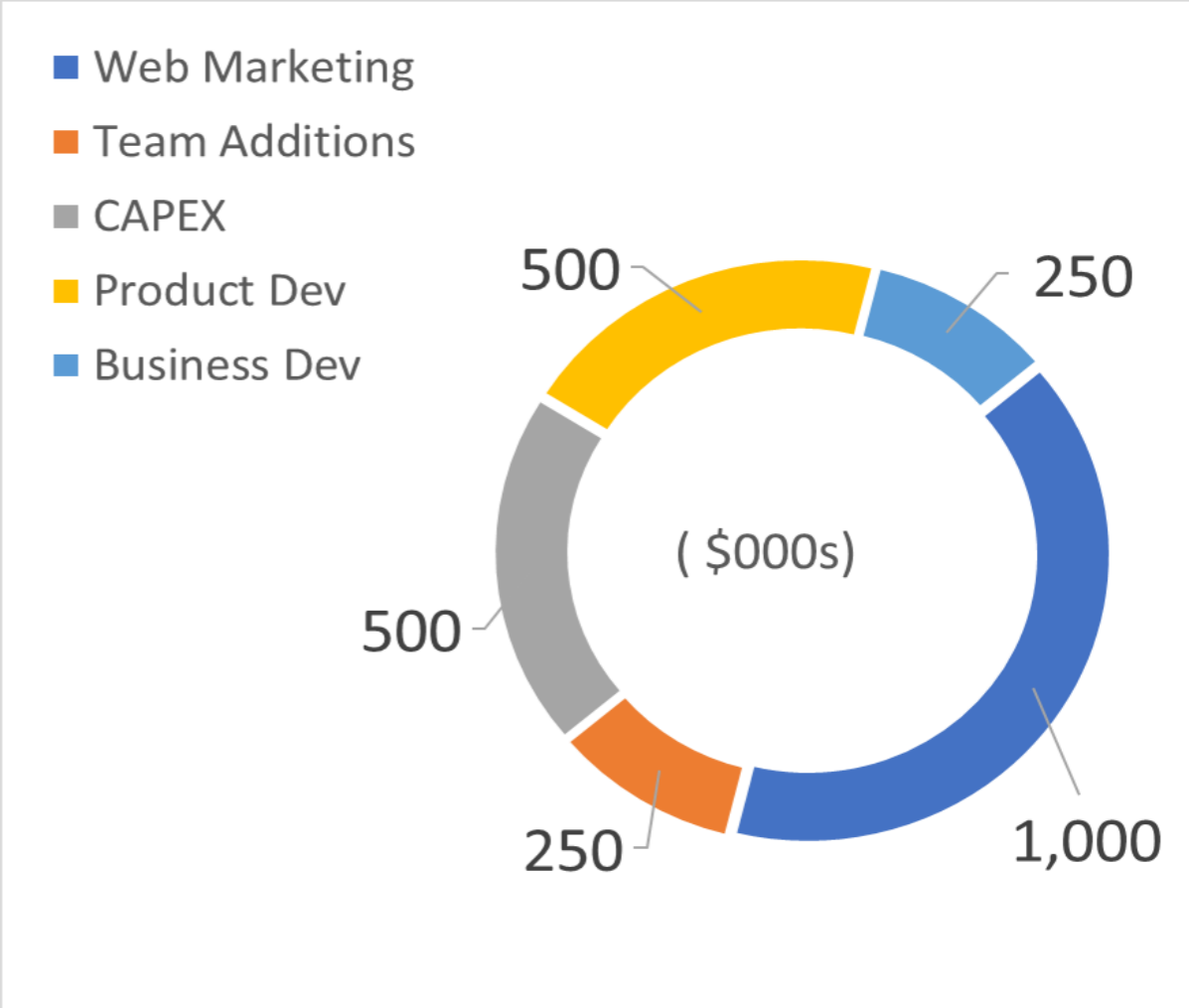


# Investment Goals

**Funds Raised to Date: \$7.1 M**

**Venture / Strategic – Q3 2024:  
Series A Preferred Shares  
\$5,000,000.**

**Supporting capacity additions and  
new product development and trials**



**Projected Use of Funds  
Q1 2024 thru Q1 2025**

# Proven Leadership Team and Advisors



**Edison Hudson**  
CEO / CTO

- Former iRobot Exec
- Automation & AI Expert
- 20+ Patents
- 7 startups, 4 Exits
- 2 IPO teams
- Director Panaceutics Nutrition Inc
- Duke MBA, Oxford AI



**Danny Barnes, RPh**  
PharmD, Chief Pharmacy Officer

- Founder Triangle Compounding Rx
- 20+ yrs in compounding pharmacy
- First NC registered 503B FDA Outsourcing Facility
- IACP Board Member



**Garrett Ruhland**  
Chief Digital Marketing Officer / CIO

- BioMarker Labs, CEO Founder
- Digital healthcare marketing expert in Bay Area
- Hedge fund Advisor, Koroit Capital
- Biochemistry, molecular biology, Duke Univ
- UCL London studies



**Arthur Kellermann, MD, MPH**  
Chief Medical Officer

- Healthcare leader, expertise in academic medicine, emergency care, public health, military medicine and health policy
- CEO of VCU Health System, Dean, School of Medicine, Uniformed Services University
- Paul O'Neill/Alcoa Chair in Policy Analysis at the RAND Corporation
- Forbes Contributor



**Eva Doss**  
Board Member

- CEO -The Launch Place venture fund
- 25 yrs in business consulting, strategic planning, equity
- Secured \$50 million in private equity
- Booz Allen, Research Triangle Institute, USAID Executive
- MIT Sloan School



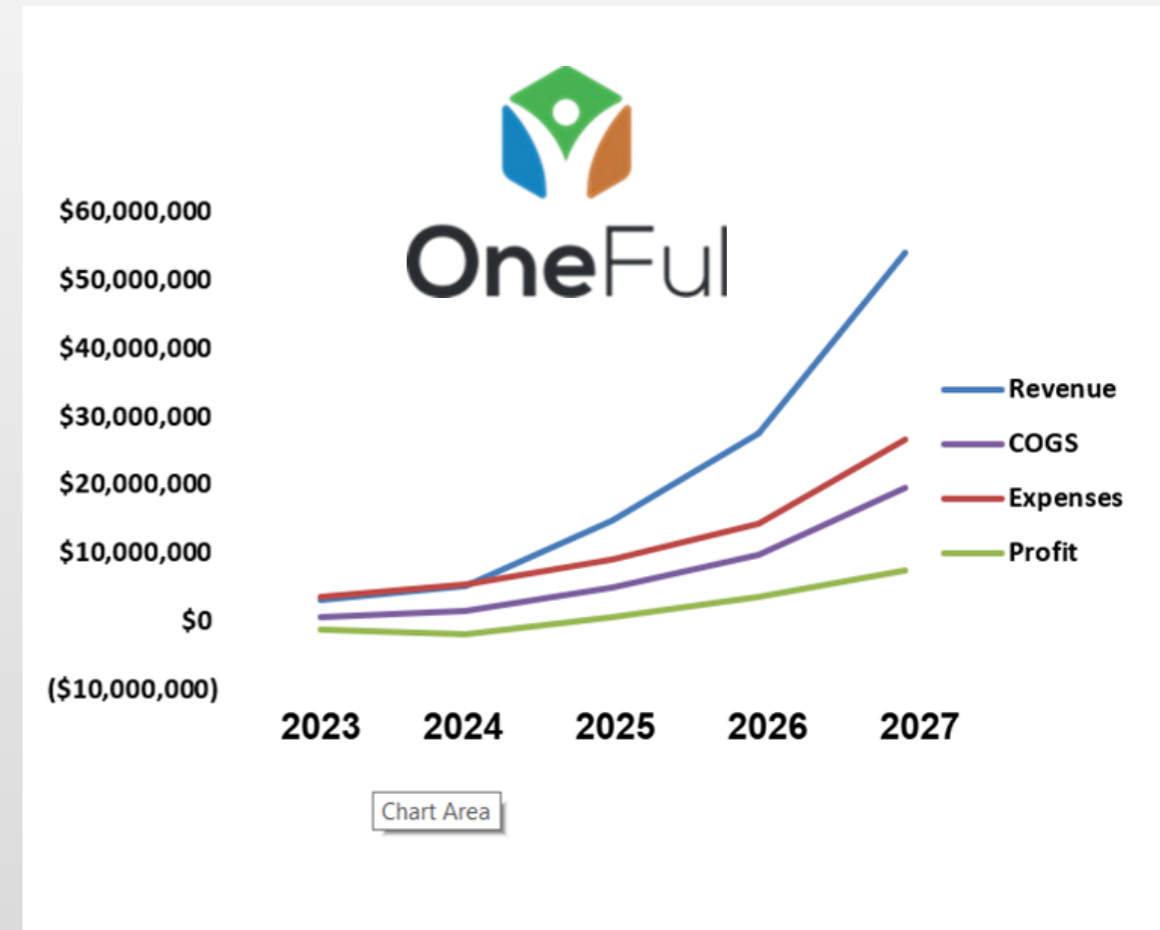
**Deon Joubert**  
Board Chairman

- Represents Sanitarium Health & Wellbeing (AUS)
- Executive General Manager
- Sanitarium is one of Australia/New Zealand's largest health food companies, and operates major hospitals
- Responsibility for a range of treasury and finance functions, banking, insurance, legal and M&A.,
- Reports to the Chief Executive Officer



# Why Invest?

- ✓ Individualized treatments that work better for patients, high adherence and fewer adverse effects.
  - ✓ Improves the quality of life for millions with chronic illness.
  - ✓ Over 100,000 Preventable deaths/ year in USA from non-adherence alone.
- 
- ✓ 13+ patents issued in personalized medicine, digital health, proven automation systems
  - ✓ The precision CVD-P<sup>3</sup> product meets all regulatory, quality milestones, patients love it
  - ✓ Proven management, accredited facilities, national expansion plan results in \$1B potential



Edison Hudson | [edison@oneful.health](mailto:edison@oneful.health) | (919) 215-9358 | [www.oneful.health](http://www.oneful.health)



**OneFul**

***Making Medicines  
Work Better For EveryONE***

**[www.oneful.health](http://www.oneful.health)**

**Edison Hudson, CEO/CTO**

**Edison@oneful.health**

**OneFul Health Inc**

Research Triangle Park  
North Carolina 27709 USA



<b>STATE OF NORTH CAROLINA</b>  <b>Department of State Treasurer</b> NC State Health Plan for Teachers and State Employees	<b>REQUEST FOR INFORMATION NO.</b> 270-20240419GLP  Due Date: May 31, 2024, 2:00 PM ET
<b>Refer <u>ALL</u> Inquiries to:</b> Kimberly Alston, Contracting Agent	Issue Date: April 19, 2024  Commodity: 851017 Health Administration Services
E-Mail: <a href="mailto:Kimberly.Alston@nctreasurer.com">Kimberly.Alston@nctreasurer.com</a> with a copy to <a href="mailto:SHPCcontracting@nctreasurer.com">SHPCcontracting@nctreasurer.com</a>	Using Agency Name: NC State Health Plan for Teachers and State Employees

**MAILING INSTRUCTIONS:** Respondents shall submit one (1) signed, original paper response, and one (1) electronic copy on a flash drive and one (1) redacted electronic copy on a flash drive, if applicable pursuant to Section 3.0.D. The address label shall clearly note the RFI number as shown below. It is the responsibility of the submitting entity to have the RFI in this office by the specified time and date of opening.

<b><u>DELIVERY ADDRESS</u></b>
<b>RFI NO. 270-20240419GLP</b> NC Department of State Treasurer State Health Plan Division Attn: Kimberly Alston, Contracting Agent 3200 Atlantic Avenue, Raleigh, NC 27604

**NOTICE TO RESPONDENTS**

Responses to this RFI will be received at the address above until May 31, 2024, 2:00 PM ET.

**QUESTIONS**

Email written questions no later than April 30, 2024, 5:00 PM ET to [Kimberly.Alston@nctreasurer.com](mailto:Kimberly.Alston@nctreasurer.com) with a copy to [SHPCcontracting@nctreasurer.com](mailto:SHPCcontracting@nctreasurer.com).

**EXECUTION**

RESPONDENT NAME:	E-MAIL:	
STREET ADDRESS:	P.O. BOX:	ZIP:
CITY & STATE:	TELEPHONE NUMBER:	TOLL FREE TEL. NO:
TYPE OR PRINT NAME & TITLE OF PERSON SIGNING:	FAX NUMBER:	
AUTHORIZED SIGNATURE:	DATE:	

## **1.0 EXECUTIVE SUMMARY**

The North Carolina State Health Plan for Teachers and State Employees (“Plan”), a division of the North Carolina Department of State Treasurer, provides health care coverage to more than 740,000 teachers and school personnel, State Employees, retirees, current and former lawmakers, state university and community college personnel, and their dependents. The mission of the State Health Plan is to improve the health and health care of North Carolina teachers, State Employees, retirees, and their dependents, in a financially sustainable manner, thereby serving as a model to the people of North Carolina for improving their health and well-being.

## **2.0 PURPOSE AND OBJECTIVES OF THE REQUEST FOR INFORMATION**

The Plan’s net spend on glucagon-like peptides (GLP-1s) and gastric inhibitory polypeptide (GIP) agonists for weight loss exceeded \$100 million in 2023 and was projected to exceed \$170 million in 2024. In order to limit this financially unsustainable expense, the Board of Trustees for the State Health Plan for Teachers and State Employees ended coverage of GLP-1s, GIP-GLP-1 agonists and other similar molecular entities used for weight loss as a benefit effective April 1, 2024.

The Board further directed Plan staff to explore options that may allow members who need these medications the most to obtain them, informed by medical necessity and long-term cost effectiveness, under a fiscally sustainable model, budgeted over at least the next five years. To that end, the Plan is issuing this Request for Information (RFI) to gather ideas and solutions from the marketplace.

This RFI is intended to collect information, recommendations, and potential solutions for the Plan to consider respecting the feasibility of providing benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss in a manner that is financially sustainable for the Plan.

The Plan is seeking responses outlining detailed solutions that would address the following:

- A. Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for the purpose of weight loss.
- B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:
  1. Pay for varying percentages of the unit cost according to medical necessity considerations.
  2. Receive the same effective net price if the Plan only chooses to pay for a medication for an additional FDA indication without paying for it for all other indications.
  3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.
- C. Potential for establishing a program outlining certain eligibility requirements, parameters, or other prerequisites for Plan members to follow in order to receive benefit coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for weight loss. As a result, the Plan seeks the ability to:

1. Require that an approved weight loss program or nutrition classes be completed before approval of payment for the medication.
  2. Develop step therapies involving lower cost medications.
  3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.
  4. Prohibit Body mass index (BMI) measurements from being estimated via telehealth visit to ensure accuracy and accountability, while enabling a data collection process that supports the successful implementation of the benefit.
- D. Potential for establishing a program wherein the Plan has the flexibility to establish parameters for utilization management of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss, which may include considerations such as, but not limited to:
1. BMI;
  2. Current weight;
  3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity;
  4. Documented enrollment and measurable participation in other nutritional or dietary programs;
  5. Consideration of evidence for one or more comorbid conditions or other obesity-related medical conditions;
  6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;
  7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or
  8. Any other considerations or parameters that would support a program to achieve the Plan's objectives of serving the members who need these medications the most.
- E. Provide cost, price structures, or other relevant expense information related to the recommendations and potential solutions submitted.

### **3.0 RFI PROCEDURES**

#### **A. Schedule**

Responses must be received by the date, time and the location specified on the cover sheet of this RFI. Respondents may be requested to present and discuss their submissions at the Plan's offices in-person or remotely. If the Plan requests such a presentation, respondents will be notified of the specific date and time at least two weeks in advance of any presentation.

#### **B. Clarification Questions**

Clarification questions will be accepted until April 30, 2024, 5:00 PM ET as specified on the cover sheet of this RFI (the "Clarification Period"). All questions must be submitted in writing. Responses to all questions received shall be addressed and issued as an addendum to this RFI. During the Clarification Period, respondents are strongly encouraged to raise any and all

questions or concerns about the RFI. Any questions or concerns not raised during this period are considered waived by the respondent.

Question submittals should include a reference to the applicable RFI section and be submitted in the format shown below:

No.	Reference	Respondent Question
1.	RFI Section, Page Number	Respondent Question . . . ?

### C. Response

The Plan recognizes that considerable effort will be required in preparing a response to this RFI. However, please note this is a request for information only, and not a request for services. The respondent shall bear all costs for preparing this RFI. **Under no circumstances will any documents, information, recommendations, or potential solutions submitted in response to this RFI, or any communications between the Plan and a respondent, create a binding agreement or contract, or expectation thereof, between the Plan and respondent or between the State of North Carolina and respondent.**

#### 1. Content and Format

The Plan expects a comprehensive, detailed explanation of the workings of each component of the response. Each component of the response will explain how it will operate to address the needs and objectives of the Plan as identified in Section 2.0. The Plan is not interested in brochures or “boilerplate” responses. Instead, responses should clearly define how the proposed solution(s) would meet the Plan’s needs. Any issues or exceptions to the Plan’s requirements should also be identified and explained.

The response may include charts, graphs, or other visuals that assist in demonstrating how a component of a response operates or how that component would meet the Plan’s objectives.

A comprehensive, detailed equipment list including software, applications and other information technology components required for the proposed solution should be provided. The Plan is not interested in participating in any field trials of new equipment or software.

The response should define all services that would be required by the proposed solution. The response should also include:

- The respondent’s understanding of the project and services by addressing the Plan’s objectives; and
- An estimated total cost of ownership for the solution including continued compliance with emerging industry standards.

#### 2. Multiple Responses

Multiple responses, or alternative individual solutions will be accepted from a single respondent provided that each response is comprehensive, meets all of the Plan’s requirements, and is truly unique. If submitting multiple responses, place each response in a separate envelope and clearly mark responses as “Response #1, Response #2, etc.

#### **D. Confidentiality**

Responses obtained by the Plan under this RFI and items derived therefrom are subject to the State Public Records Act, Chapter 132 of the North Carolina General Statutes (the "SPRA").

If a response contains any proprietary or confidential information protected from public disclosure under the SPRA, the respondent shall submit a redacted electronic copy on a flash drive to the Plan with its response. Any proprietary or confidential information under the SPRA must be clearly redacted by the respondent in black markings fully covering and obscuring such information within the redacted electronic copy of the RFI response. By submitting a redacted electronic copy, respondent warrants that it has a good faith opinion that the redacted information in fact meet the requirements of the SPRA and the SPRA prevents their public disclosure. Blanket assertions of confidentiality are not permitted.

In the Plan's unfettered discretion and without notification to any respondent, the Plan may post any responses obtained by the Plan under this RFI, and items derived therefrom, on the Plan's public website ([www.shpnc.org](http://www.shpnc.org)). In posting such items to the Plan's website, the Plan will post the redacted version of such items, if respondent has provided redactions in compliance with this section. If no redacted version of such items has been provided to the Plan in compliance with this section, the Plan will post such items on the Plan's website in the manner they were provided to the Plan.

Redacted copies provided by respondents to the Plan may be released in response to SPRA requests without notification to the respondent. Further, respondent's information that cannot be shown to be prohibited from disclosure by the SPRA may be subject to public disclosure under the terms of the SPRA.

If a legal action is brought to compel the Plan to disclose any of the respondent's redacted information, the Plan will notify the respondent of such action and consent to intervention of the respondent in the action and to the respondent's defense of the confidential status of the redacted information. In such legal action, the duty and responsibility to defend such information shall solely be the respondent's, and the Plan shall have no liability to the respondent for the Plan's failure to defend such action.

#### **E. Respondent Materials**

All responses, inquiries, or correspondence relating to or referenced in this RFI, and all documentation submitted by the various respondents shall become the property of the Plan when received. Ideas, approaches, information, recommendations, potential solutions, and options (but not proprietary material) presented by respondents may be used in whole or in part by the Plan in developing a future solicitation, should the Plan decide to proceed with a solicitation. Further, combinations of various responses from respondents may also become part of a solicitation, based on the needs of the Plan.

# ADDENDUM

**REQUEST FOR INFORMATION NUMBER:270-20240419GLP  
ADDENDUM NUMBER:1**



**REQUEST FOR INFORMATION (RFI) ADDENDUM**

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Issuing Agency:	North Carolina State Health Plan for Teachers and State Employees
RFI Number:	270-20240419GLP
RFI Description:	GLP-1 Solutions
RFI Opening Date and Time:	May 31, 2024, 2:00 PM ET
Addendum Number:	1
Addendum Date:	May 6, 2024
Purchasing Agent:	Kimberly Alston

**FAILURE TO RETURN THIS ENTIRE ADDENDUM MAY SUBJECT YOUR RESPONSE TO REJECTION.**

1. Addendum Number 1 is in response to questions submitted. Responses to questions begin on the next page.
2. Return one signed copy of this Addendum with your RFI response.

\*\*\*\*\*

**Execute Addendum Number 1. RFI Number 270-20240419GLP:**

Respondent: OneFul Health Inc.

Authorized Signature:           Edison T. Hudson          

Name and Title (Print): Edison T. Hudson

CEO

Date: May 31, 2024

---

**North Carolina State Health Plan for Teachers and State Employees**  
**RFI Number: 270-20240419GLP**

**RESPONSE DATE:** MAY 31, 2024

(UPDATED VERSION JUNE 03 2024 - CHANGES IN PURPLE)

**SUBMITTED BY:**

OneFul Health Inc.  
3700 Regency Parkway, Suite 140  
Cary, North Carolina 27518 USA  
[www.oneful.health](http://www.oneful.health)

Please direct all questions to these individuals:

Edison T. Hudson, CEO  
Email: [edison@oneful.health](mailto:edison@oneful.health)

Phone: 1-919-215-9358

Danny M. Barnes, PharmD BCSCP Rph, Chief Pharmacy Officer  
Email: [dbarnes@trianglecompounding.com](mailto:dbarnes@trianglecompounding.com)

Phone: 1-919-427-4623

**I. OVERVIEW**

*OneFul Health Inc., a healthcare innovations company based in Cary and RTP, North Carolina, is excited to present a comprehensive response to the North Carolina State Health Plan for Teachers and State Employees. Our proposal includes innovative solutions, strategic recommendations, and a budget-friendly approach to enhance the health outcomes of the Plan's members.*

*We propose to supply FDA-approved GLP-1 and GIP/GLP-1 active pharmaceutical ingredients (APIs), which are lab-certified and market-leading. These APIs will be offered in a long-term contract at a cost that is less than 20% of the current best pricing to the Plan that is publically known, ensuring significant savings.*

*We suggest a flexible pricing solution based on condition-agnostic dosing-level costs with adjustable co-pays to accommodate the Plan's budgetary constraints. This approach allows for adaptability and individualized care as an alternative to fixed drug pricing.*

*To manage this flexible system and ensure compliance, we recommend implementing a proven 'soft-PBM' administration system specifically designed for weight-loss programs using GLP-1 interventions. This system ensures compliance with online patient screening, pre-approval protocols, and medical guidelines.*

*Furthermore, we propose to establish a network of NC-based brick-and-mortar partners. These partners will enhance member approval, compliance, coaching, and in-person medical follow-up, providing a holistic approach to healthcare.*



*Lastly, OneFul is developing a non-drug step-up/step-down complementary medical food product in collaboration with several small RTP-based businesses. Past N.C. Biotech Center loans supported the early development of our patented capabilities to make such products. The GLP-OneFul products are being designed to address unmet needs for alternative maintenance therapies once patients stop GLP-1RA injections and as a gentle, low-side effect therapy suitable for treating pediatric obesity. Clinical trials have shown that this product can endogenously increase GLP-1 and PYY satiety peptides. We believe this innovative product will be a game-changer shortly, enabling effective and economical weight-loss maintenance and Type-2 Diabetes augmentation for large patient populations.*

*We look forward to the opportunity to work with the Plan to improve the health and well-being of its members.*

*Thank you for considering our response to the RFI.*

## II. BACKGROUND

OneFul Health Inc. is committed to developing and commercializing affordable and highly effective treatments for cardio-metabolic health for over ten years. We invented and patented systems to affordably address the most significant personal and public healthcare costs and the greatest cause of death globally. We personalized generic and approved drugs to match individual patient needs and metabolism. With novel regulatory strategies, current Good Manufacturing Practices (cGMP), and automation, OneFul ensures traceable quality. Our product strategy is to bring highly effective therapies scaled to mass markets at price points typically a fifth of treating chronic diseases.

We are participating in the GLP-1 agonist revolution directly by investing in the lab-certified bulk inventory of the **FDA-approved form of semaglutide and tirzepatide**, the active ingredient of popular drugs Ozempic®/Wegovy® and Mounjara®/Zepbound®. We are making personalized and affordable forms of these GLP-1 and GIP-GLP-1 injectable pharmaceuticals in our wholly owned accredited sterile pharmaceutical facility in Cary, NC, [Triangle Compounding Pharmacy](#), ('TCP'). TCP was the first in North Carolina and one of the earliest nationally to implement a 503B Human Drug Outsourcing Facility and is an approved vendor to UNC Healthcare, Duke Medical, Veterans Administration, and over 7,000 individuals and physicians in nine Southeastern states. The National Pharmacy Compounding Accreditation Board and the North Carolina Board of Pharmacy annually inspect and accredit our sterile and non-sterile facilities.

TCP has a history of saving healthcare systems millions annually, providing pharmaceutical preparations on national backorder. TCP supplied N.C. Medicaid patients for years with sterile hydroxyprogesterone injections, a drug that at the time was the standard of care to prevent pre-term labor, saving the North Carolina healthcare system over 10 million dollars over several years in drug cost alone. Physicians at UNC Healthcare are currently prescribing semaglutide and tirzepatide from TCP in vial form to some of their patients who cannot get coverage or afford the standard auto-injector products.

OneFul is also developing innovative oral therapies to complement GLP-1 agonist injections and serve as pre-hab or step-down aids to metabolic health. We are advised on this development by former leading metabolic drug developers at Glaxo-Smith Kline, distinguished endocrinologists at UNC, and pharmaceuticals experts at the Eshelman School of Pharmacy. In November 2023, OneFul completed the buy-back of Panaceutics.com's assets, a personalized nutrition and clinical foods supplier. Panaceutics made branded products for Abbott Nutrition, Bayer Consumer Health, Microbiome Labs (a Novo-Nordisk company), and niche direct-to-consumer nutraceutical companies. This platform, designed by OneFul inventors, creates individually prescribed snack-sized (50-gram) squeeze pouches delivering high doses of ingredients to

specific locations in the digestive tract in a single packet, equivalent to taking up to 20 conventional capsules. Multiple clinical and animal trials have shown that our GLP-OneFul formulation stimulates native GLP-1 and PYY satiety hormones at levels similar to gastric bypass surgery. The attached whitepaper describes this development.

Founded by native-born professionals in the heart of North Carolina, OneFul Health is a pioneer in developing patient-focused healthcare solutions, leveraging cutting-edge robotic additive manufacturing technologies and digital health systems. Our founder and CEO, Edison Hudson, is a distinguished Morehead Scholar from UNC-Chapel Hill, an MBA graduate from Duke Fuqua School of Business, and studies robotics and machine intelligence at Oxford University, U.K. He has been part of two IPOs in his career.

Our pharmacy team is led by Danny Barnes, a PharmD BCSCP Rph, who brings his background as a biologist from N.C. State University and his PharmD from Campbell University. His experience as a national-level regulatory expert further strengthens our team. His team includes several other PharmDs and former FDA advisors.

Our advisory board comprises seasoned professionals from the pharmaceutical industry and academia, including eminent physicians with decades of medical practice and global experts in developing endocrine products, including GLP-1RAs. This collective expertise positions OneFul Health and its partners to engage in productive collaborations with the Plan's team. Our goal is to co-create solutions that are both medically effective and economically sustainable. We are ready and eager to bring our knowledge and skills to the table for the benefit of all.

### III. RFI SPECIFIC RESPONSES

In accordance with the Plan's RFI Number: 270-20240419GLP, to the topics enumerated (in red) our responses are presented (in black):

- A. Permit the Plan to provide benefit coverage to Plan members to use GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss.
- i. GLP-1 agonist peptide mimics as semaglutide, conforming to the FDA-specified base active pharmaceutical ingredient ('API') and chemical form, and is certified by an approved and certified analytical laboratory and supplied to individual patients based on prescriptions typically received by the SureScripts e-prescriptions system. Bulk semaglutide inventory is securely kept in refrigerated storage at TCP in Cary, NC., processed and repackaged under ISO 5 cleanrooms into industry standard 1 ml vials, and provided to patients and practitioners for injection delivered in approved insulin class syringes.
  - ii. GIP/GLP-1 agonist peptide mimics, as tirzepatide, conforming to the FDA-specified base active pharmaceutical ingredient ('API') and chemical form is certified by an approved and certified analytical laboratory and supplied to individual patients based on prescriptions typically received by the SureScripts e-prescriptions system. Bulk tirzepatide inventory is securely kept in refrigerated storage at TCP in Cary, NC., processed and repackaged under ISO 5 cleanrooms into industry standard 1 ml vials, and provided to patients and practitioners for injection using approved insulin class syringes. Sterility, endotoxin, and particulate matter tests are performed by an independent certified analytical lab at the batch level, typically around 250 doses. Prescriptions generally are delivered or picked up at approved locations.

- iii. The above chemical forms contain the equivalent active peptide ingredients of the brand names Ozempic®/Wegovy®, Mounjara®/ Zepbound®. The Saxenda equivalent bulk ingredient is available but not in inventory at TCP and has not been processed or dispensed. The lab testing, processing and dispensing systems used for semaglutide and tirzepatide are thought to be very similar for Saxenda.
- iv. The above peptides are also dispensed for obesity to promote weight loss, as well as conditions of Type 2 Diabetes and relevant cardiovascular conditions, as may be prescribed by licensed physicians at approved and non-standard dosages.

B. Establish a pricing framework that would permit the Plan to provide such benefit coverage in a fiscally responsible manner in order to maintain financial sustainability. For example, the Plan seeks the ability to:

1. Pay for varying percentages of the unit cost according to medical necessity considerations.

- i. OneFul/TCP can propose a pricing scheme that varies according to medical necessity and physician's dosing recommendations. As a re-packager purchasing bulk APIs, we have complete knowledge and systems to track the materials, labor, testing, and administrative costs associated with filling each specific prescription.
- ii. The cost of the bulk APIs comprise a significant portion of material cost-of-goods ('CoGs') and varies proportional to the prescribed dose of the API.
- iii. For weight loss prescriptions, as per Wegovy® standard dosing protocols, the starter dosage of 0.25 mg of semaglutide API constitutes about 30% of the CoGs, whereas the maximum dosage of 2.4 mg of semaglutide API is about 75% of the CoGs.
- iv. For weight loss prescriptions, as per Zepbound®'s standard dosing protocols, the starter dosage of 2.5 mg of tirzepatide API constitutes about 65% of the CoGs, while the maximum dosage of 15 mg of tirzepatide API is about 87% of the CoGs.
- v. A significant cost of the commercially branded weight loss GLP-1 and GIP-GLP-1 medications is the FDA-approved precision auto-injector variably dosable device. Inadequate availability of these auto-injectors is a reported cause of the current shortage and the lack of fill capacity for this specialized device.
- vi. OneFul/TCP uses a low-cost, while considered less convenient and user-friendly by some users than the subcutaneous auto-injector devices, the low-cost vial-syringe supplied by TCP is plentifully available and has been a patient self-use device for decades to deliver insulin at home. This approach also allows for non-standard dosing prescriptions, sometimes deemed medically necessary, to reduce adverse side effects in some patients.
- vii. API supply chain issues currently favor the sources curated by OneFul/TCP. We are presently seeing accelerating price reductions for some of these APIs and a noted price elasticity driven by the volume of our bulk purchases. In general, we are witnessing bulk API price reductions of as much as 25%, driven by the increased size of purchases. OneFul/TCP is open to pricing that reflects the impact of larger order quantities that would increase our purchasing leverage from a contract with the Plan.

- viii. The enormous investments by Novo Nordisk, Eli Lilly, and several others in peptide and fill capacity will likely result in market pricing competition. It may also present an issue for our business model if and when the FDA declares that a shortage condition no longer exists for these approved commercial drugs. OneFul/TCP has developed regulatory strategies and product plans that we can implement in less than twelve months to mitigate a change in shortage status and ensure the continuity of our ability to supply API to address weight loss and other indications. OneFul/TCP will share these strategies as part of a definitive procurement contract's warranties.

2. Receive the same effective net price if the Plan only chooses to pay for a medication for an additional FDA indication without paying for it for all other indications.

- i. OneFul/TCP proposes "dosage-driven pricing" based on CoGs and cost to profitably dispense at a level to ensure that our facilities and staff fully meet all FDA and N.C. Board of Pharmacy regulatory requirements. Our pricing proposal will be agnostic to the indication to which it may be prescribed. Our professional PharmD staff and Quality Assurance shall reserve the right to review any prescription as per our standard operating procedure as regards the safety and any known interactions for a given individual patient and to reject any non-compliant formulations or orders.
- ii. OneFul/TCP acknowledges that the response to this RFI is understood not to be a response to a formal bid requested by the Plan. Further, OneFul/TCP is not committed to achieving specific pricing levels. However, we offer these achievable estimated pricing for standard dosing levels, which is achievable given today's market conditions and our business model. Here is a Dose-Driven Pricing, Condition Agnostic example:

<b>Conditions Indicated</b>			
<b><u>T2 Diabetes</u></b>			<i>Ozempic Guidelines</i>
		<b>Dose (mg)</b>	<b>Monthly Script Price*</b>
<b>Initial dose:</b>	<b>0.25</b>	<b>\$</b>	<b>105.00</b>
<b>Maintenance dose</b>	<b>0.50</b>	<b>\$</b>	<b>115.00</b>
<b>High dose:</b>	<b>1.00</b>	<b>\$</b>	<b>140.00</b>
<b>Maximum dose:</b>	<b>1.25</b>	<b>\$</b>	<b>150.00</b>
			<i>Wegovy Guidelines</i>
<b><u>Obesity</u></b>			<b>Monthly Script Price*</b>
	<b>Dose (mg)</b>		
<b>Initial dose:</b>	<b>0.25</b>	<b>\$</b>	<b>105.00</b>
<b>Maintenance dose</b>	<b>1.25</b>	<b>\$</b>	<b>151.23</b>
<b>High dose:</b>	<b>2.40</b>	<b>\$</b>	<b>206.47</b>
<b>Maximum dose:</b>	<b>2.40</b>	<b>\$</b>	<b>206.47</b>
			<i>Mounjaro/ Zepbound Guidelines</i>
<b><u>Obesity/TD Diabetes</u></b>			<b>Monthly Script Price*</b>
	<b>Dose (mg)</b>		
<b>Initial dose:</b>	<b>2.50</b>	<b>\$</b>	<b>110.00</b>
<b>Maintenance dose</b>	<b>5.00</b>	<b>\$</b>	<b>150.00</b>
<b>High dose:</b>	<b>10.00</b>	<b>\$</b>	<b>275.00</b>
<b>Maximum dose:</b>	<b>15.00</b>	<b>\$</b>	<b>400.00</b>
*Subject to definitive procurement contract, volume, services, and administrative fees dependent			

- iii. OneFul's current experience in purchasing bulk GLP-1 compounds indicates that pricing is highly sensitive to the volume of each buy and commitments for future purchases. We have received cost reductions from some suppliers as large as 25% as we ramp up the quantity of these drugs ordered. OneFul is open to developing a contract with the Plan on a cost-to-dispense basis, such that the price is elastic to the level of committed demand and the market pricing OneFul can achieve based on the financial commitment of the Plan to enable scaled-up purchasing.
- iv. The cost of these medications is also affected by the specialized expenses of pharmacists and pharmacists' technical labor employed. These costs may be substantially reduced, and capacity may rapidly added to our existing laboratory by known proven automation. Led by experts in robotic automation technology that can further reduce the costs of GLP-1 sterile injection products while achieving high-quality standards. Within six to nine months of a contract, OneFul will implement a first-phase automation plan to increase capacity to service up to 20,000 GLP-1 injection patients monthly. A second phase of automation is projected to increase the capacity to nearly 40,000 patients/month. This capacity increase will utilize fully compliant cGMP systems known to OneFul and in small-scale pharmaceutical manufacturing.
- v. OneFul/TCP has close relationships with other 503A Sterile and 503B Outsourcing Facilities and would agree to enter into contracts to supply these APIs in the same form and under the same quality procedures and on similar terms as a backup to our own TCP facility in Cary, NC.

3. Audit claims, rebates, and prior authorizations for accuracy and compliance with applicable laws and regulations.

- i. This disclosure acknowledges that OneFul/TCP does not have adequate administrative capabilities to fulfill this requirement within our small business enterprise. We use internal I.T. and web-based services and systems to receive, validate, process, and track prescriptions. While these systems provide the necessary infrastructure, our systems are inadequate to facilitate the tasks of administering members' claims, rebates, prior authorizations, and compliance.
- ii. We have extensive knowledge of partners interested in subcontracting to OneFul or directly to the Plan to fulfill these administrative member compliance requirements.
- iii. We have researched available systems for these purposes, which are, in effect, forms of cloud-based "software pharmacy benefit management" ('Soft-PBM'). These systems can interface with our systems through the [Surescript e-prescribing system](#) to meet HIPPA compliance and provider validation.
- iv. OneFul recommends that the Plan consider a Soft-PBM explicitly designed to manage the unique acceptance and compliance issues associated with successful programs in weight loss. The attached whitepaper, "The History and Current Burden of Medically Managed Weight Loss", justifies this recommendation.
- v. Our top recommendation for such a system to meet the Plan's administrative requirements is [Digbi Health Inc.](https://digbihealth.com/pages/partner) ( <https://digbihealth.com/pages/partner> ). The co-founder of Digbi Health is a North Carolina native with extensive knowledge of the administrative challenges for effective weight-loss programs. If desired, we are discussing with him to fulfill a consulting role to work with OneFul and the Plan.

- i. The weight-loss management administration concept for the Plan proposed by partner Digbi Health could mimic some of the features of Connecticut's employee health plan program for weight loss. Connecticut has launched a novel clinical lifestyle management program, Flyte, aimed at state health plan members interested in using weight loss medications like Ozempic® or Wegovy®. This program provides digital resources for weight management and allows participants to consult healthcare providers to develop individualized care plans. See, [Weight-loss drugs are expensive, but Connecticut has a plan \(advisory.com\)](#)

<https://www.advisory.com/daily-briefing/2023/11/17/connecticut-weight-loss#:~:text=In%20July%2C%20Connecticut%20introduced%20a%20new%20clinical%20lifestyle,meet%20with%20providers%20to%20receive%20personalized%20care%20plans>

- vi. OneFul is developing a complementary GLP-OneFul product line of personalized step-up medical foods to mitigate side effects and as a safety net to prevent catastrophic re-gaining of weight once injection-based treatment ends. This product is being developed to re-stimulate endogenous GLP-1 and other satiety hormones. This article discusses the targeted market and needs:

["Ozempic® Patients Need an Off-Ramp"](#)

<https://www.msn.com/en-us/health/other/Ozempic®-patients-need-an-off-ramp/ar-BB1mRgHB?ocid=msedgntp&pc=U531&cvid=1795492d68c0488ed335d9654b0e59e4&ei=49>

- vii. OneFul intends to work with Digbi Health to develop the protocols for onboarding these patients, which will be similar to the Plan's requirements, and is open to coordinating these efforts with the Plan.

- viii. OneFul has also evaluated other Soft-PBM solutions that meet the essential elements of this part of the RFI. There are web software solutions designed to perform the tasks of Pharmaceutical Benefits Management (PBM). These platforms offer a range of functionalities to manage pharmacy benefit programs. Here are examples:

- a. [McKesson's ProPBM: This software platform provides real-time pharmacy claims processing and gives PBMs full control over their pharmacy benefit programs<sup>1</sup>. It allows for the management of complex prescription drug formularies, varying co-pay schedules, accumulated pharmacy benefits, and drug utilization reviews \(DUR\), among other features.](#)
- b. **Encora's Automated Solutions:** Encora suggests that PBMs should transition to automated solutions to handle the evolving needs of the healthcare industry. [Their solutions offer robust and scalable architecture that supports web applications for all entities in the healthcare system, including cross-platform integration for billing, claims, eligibility processing, and formulary management.](#)
- c. These Soft-PBM tools are designed to streamline the administration of pharmacy benefits, ensuring compliance with healthcare regulations and providing cost-effective healthcare solutions.
- d. Large employers have used these tools to manage member health benefits. They are adaptable to programs such as weight loss, but likely need considerable software customization to address the weight-loss-specific program's programmatic requirements and processes.

- B. Potential for establishing a program outlining certain eligibility requirements, parameters, or other prerequisites for Plan members to follow in order to receive benefit coverage of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities, for weight loss. As a result, the Plan seeks the ability to:
1. Require that an approved weight loss program or nutrition classes be completed before approval of payment for the medication.
  2. Develop step therapies involving lower cost medications.
  3. Require that medications be prescribed by a practitioner with appropriate levels of expertise.
- i. OneFul's response to this portion of the RFI is the same as our response and recommendation in B-3 above, except for the following additional proposal.
4. Prohibit Body mass index (BMI) measurements from being estimated via telehealth visit to ensure accuracy and accountability, while enabling a data collection process that supports the successful implementation of the benefit.
- ii. OneFul proposes to qualify, inspect, and integrate a North Carolina network of physical locations and practices that can act as face-to-face patient centers for some member qualification functions, including but not limited to BMI assessment.
- iii. In an initial pilot, OneFul proposes to work with Triangle area firms known to us that can provide patient pre-qualification testing, lifestyle assessment, dietary, and fitness profiling. OneFul would collaborate with the Plan to establish the criteria for qualifying these partner centers.
- iv. In a first phase pilot program, some potential example partners in the Wake, Johnson, Durham, Orange, and Chatham county areas have been identified as potential partners to provide one-time services and follow-up or reassessment, including these:
- [About Us - True You Weight Loss](#), Cary, NC, Dr Christopher McGowan
  - [Raleigh, NC Weight Loss Clinic | Programs by Doctors | North Carolina Weight Loss \(optionsmedicalweightloss.com\)](#)
  - [Medical Weight Loss in Cary, NC | Prejuve MedSpa and Wellness \(prejuvespa.com\)](#)
  - [Weight Loss & Wellness Clinic - Cary NC | Vitalize Wellness \(vitalizewellnessnc.com\)](#)
  - 3 to 7 other firms have been identified for due diligence and vetting.
  - Discussions with UNC Healthcare and other large systems at a senior level have been initiated to see what role their clinics might play in providing physical locations for the assessment and management of patients.
- C. Potential for establishing a program wherein the Plan has the flexibility to establish parameters for utilization management of GLP-1, GIP-GLP-1 agonists, and other similar new molecular entities for weight loss, which may include considerations such as, but not limited to:

1. BMI;
2. Current weight;
3. Documented history of lifestyle modifications, which may include reduced calorie intake and increased physical activity;
4. Documented enrollment and measurable participation in other nutritional or dietary programs;
5. Consideration of evidence for one or more comorbid conditions or other obesity- related medical conditions;
6. Data analytics and reporting tools supporting successful claims adjudication and program evaluation;
7. Requirements for in-person treatment visits to verify efficacy of medications for individuals; or
8. Any other considerations or parameters that would support a program in achieving the Plan's objectives of serving the members who need these medications the most?

ii. Our top recommendation for such a system to meet these requirements to meet the plans is a system already developed, tested, and field-proven for managing the specific demands of an effective weight loss program. Based on our reviews of multiple systems and our research and due diligence, we recommend [DigbiHealth Inc.](https://digbihealth.com/pages/partner) ( <https://digbihealth.com/pages/partner> ).

iii. The weight-loss management administration concept with Digbi Health could mimic some of the features of Connecticut's employee health plan program for weight loss. Connecticut has launched a novel clinical lifestyle management program, Flyte, aimed at state health plan members interested in using weight loss medications like Ozempic® or Wegovy®. This program provides digital resources for weight management, allowing participants to consult with healthcare providers to develop individualized care plans. See: [Weight-loss drugs are expensive, but Connecticut has a plan \(advisory.com\)](https://www.advisory.com/daily-briefing/2023/11/17/connecticut-weight-loss#:~:text=In%20July%2C%20Connecticut%20introduced%20a%20new%20clinical%20lifestyle,meet%20with%20providers%20to%20receive%20personalized%20care%20plans)

<https://www.advisory.com/daily-briefing/2023/11/17/connecticut-weight-loss#:~:text=In%20July%2C%20Connecticut%20introduced%20a%20new%20clinical%20lifestyle,meet%20with%20providers%20to%20receive%20personalized%20care%20plans>

iv. Other such systems may better match the Plan's needs and OneFul's. Our expert in web-based digital health systems is a Duke University neurobiologist and former CEO of BioMarker Labs, is a Bay Area, CA consultant with a considerable work history with OneFu. He can engage in a more extensive comparison and technical deep dive of some other systems once we better understand specific needs of the Plan.

v. The former co-founder of Digbi Health is a North Carolina native with extensive knowledge of the administrative challenges for effective weight-loss programs. If desired, we are discussing with him to fulfill a consulting role to work with OneFul and the Plan.

vi. We are familiar with several vendors of digital I.T. tools in addition to Digbi Health, which offer integrated remote monitoring of patients in weight loss programs using Internet of Things (IoT) methods to collect daily data. The pervasive use of continuous glucose monitors (CGMs) is a critical tool to monitor adherence and provide critical alerts for adverse severe conditions. One of our advisors is the former manager of Abbott's Free Libre market-leading CGM. His consulting services will give in-depth direct application knowledge to collect real-world interactive data about



patients' progress in a weight-loss or co-morbidity program for Type 2 Diabetes.

- vii. As an illustration of the tools already developed and available in the Digbi Health system, here is a list of some of the screening, tracking, coaching, and follow-up tools provided by Digbi Health with its remote services:

### SCREENING

- Individuals can perform an **at-home gut biome and genetic test** to assess their digestive health and genetic predispositions.
- Monitoring **insulin levels** is made convenient with the use of **continuous glucose monitoring systems, which allow for the** real-time tracking of blood sugar levels.
- Comprehensive **risk analysis** is available, focusing on factors such as **obesity, gut health, and mental health** to provide a holistic health assessment.

### DEVICES & CONNECTIVITY

- A **glucose monitoring device** is provided to continuously track glucose levels, essential for managing diabetes.
- This device seamlessly **integrates with Apple & Google health** platforms, ensuring that health data is easily accessible and manageable.
- The system is **connected to your physician**, enabling them to monitor your health metrics remotely and provide timely advice.

### HEALTH COACHING

- Members have **12-month chat access to expert nutritionists, health coaches, and care teams**, offering personalized guidance and support.
- **Meal analysis** is tailored based on individual biology, ensuring dietary recommendations are optimized for personal health needs.

### CARE SUPPORT & CONTENT

- Comprehensive **health tracking** includes monitoring sleep patterns, stress levels, food cravings, and hormone fluctuations.
- Members gain **access to a private member community**, fostering a supportive environment for sharing experiences and advice.
- Various **food guides and a recipe planner** are available to assist in making informed dietary choices.
- A library of **self-help educational videos** is provided, covering various topics to empower individuals to manage their health.

- viii. Other potential companies with these types of services include [Noom](#), [RO](#), [Hims & Hers](#), [LifeMed](#), and others we have evaluated and are open to continuing to [consider as potential administration and follow-up partners](#).

**D. Provide cost, price structures, or other relevant expense information related to the recommendations and potential solutions submitted.**

- i. OneFul/TCP proposes "dosage-driven pricing" based on CoGs and cost to profitably dispense at a level to ensure that our facilities and staff fully meet all FDA and N.C. Board of Pharmacy regulatory requirements. Our pricing proposal will be agnostic to the indication to which it may be prescribed. Our professional PharmD staff and Quality Assurance shall reserve the right to review any prescription as per our standard operating procedure as regards the safety and any known interactions for a given individual patient and to reject any non-compliant formulations or orders.
- iii. OneFul/TCP acknowledges that the response to this RFI is understood not to be a response to a formal bid requested by the Plan. Further, OneFul/TCP is not committed to achieving specific pricing levels. However, we offer these achievable estimated pricing for standard dosing levels, which is feasible given today's market conditions and our business model. Here is a Dosage-Driven Pricing Example: our current estimate of the price to be billed to the Plan given the projected potential volumes of prescriptions, the current market conditions, bulk ingredient supplies, administrative production costs, specialized pharmacists, quality, and management labor.

<i>Wegovy Guidelines</i>		
<b>Obesity</b>	<b>Dose (mg)</b>	<b>Monthly Script Price*</b>
<b>Initial dose:</b>	<b>0.25</b>	<b>\$ 105.00</b>
<b>Maintenance dose</b>	<b>1.25</b>	<b>\$ 151.23</b>
<b>High dose:</b>	<b>2.40</b>	<b>\$ 206.47</b>
<b>Maximum dose:</b>	<b>2.40</b>	<b>\$ 206.47</b>
<i>Mounjaro/ Zepbound Guidelines</i>		
<b>Obesity/TD Diabetes</b>	<b>Dose (mg)</b>	<b>Monthly Script Price*</b>
<b>Initial dose:</b>	<b>2.50</b>	<b>\$ 110.00</b>
<b>Maintenance dose</b>	<b>5.00</b>	<b>\$ 150.00</b>
<b>High dose:</b>	<b>10.00</b>	<b>\$ 275.00</b>
<b>Maximum dose:</b>	<b>15.00</b>	<b>\$ 400.00</b>
*Subject to definitive procurement contract, volume, services, and administrative fees dependent		

- ii. The cost of these medications is also affected by the specialized costs of pharmacists and pharmacists' technical labor employed. These costs can be substantially reduced, and capacity can be rapidly added to our existing laboratory by known proven automation. OneFul is led by experts in robotic automation technology that can further reduce the costs of GLP-1 sterile injection products while achieving high-quality standards. Within six to nine months of a contract, OneFul will implement a first-phase automation plan to increase capacity to service up to 20,000 GLP-1 injection patients monthly. A second phase of automation is projected to increase the capacity to nearly 40,000 patients/month. Fully cGMP-compliant systems available to OneFul will be utilized.

## IV. PROFORMA EXECUTION PLAN

Our execution strategy incorporates proven methodologies, qualified personnel, known resources, and a responsive approach to managing deliverables. We use in-house expertise organized as a small project team with executive oversight to drive innovations and project execution. We work with known outside contractors and consultants with prior working relationships and high confidence in their work products for one-time and specialty functions.

- **Resources:**

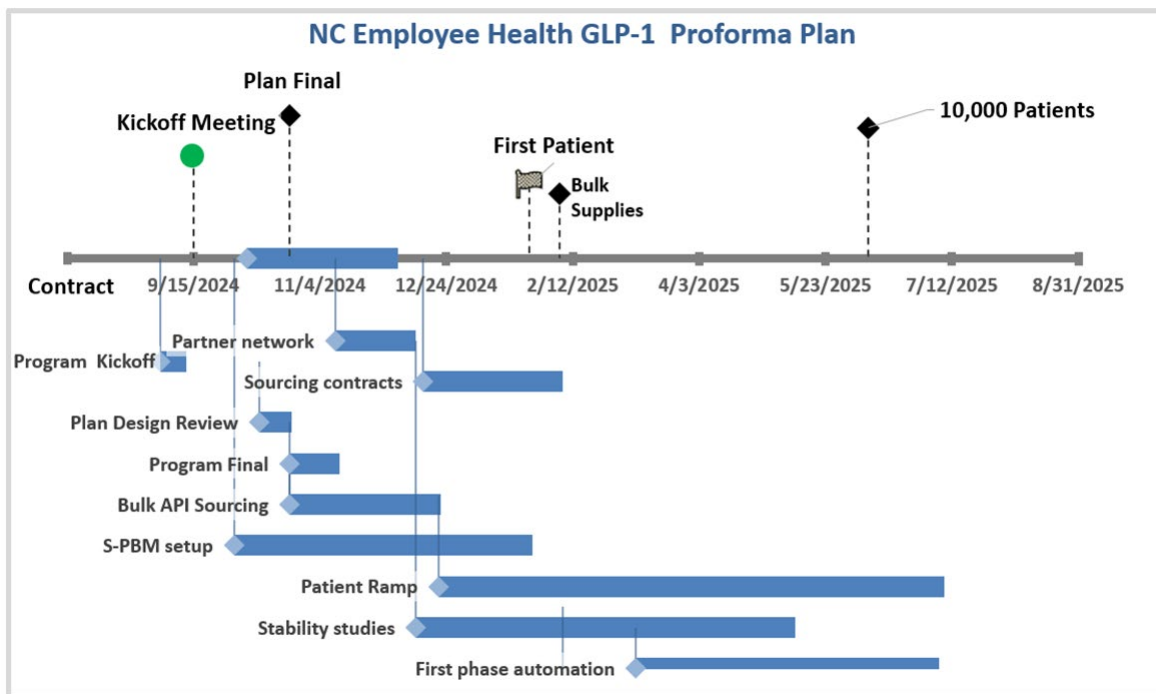
- Inhouse accredited 503A Compounding Pharmacy and licensed PharmD regulatory expert in cGMP operations.
- The current production capacity at TCP for GLP-1, GIP/GLP-1 is limited to approximately 4,500 monthly patients, primarily limited by trained personnel.
- The current bulk inventory of GIP-1, GIP/GLP-1 is only adequate to support an early pilot program plan for up to 500 patients per month, beginning in Q4 2024.
- Several qualified sources for these bulk API are either current vendors or identified alternative sources, though significant investment in inventory is warranted to meet the projected Plan's need.
- Two competing private equity firms have recently reviewed a facility and manpower plan to significantly expand the sterile processing capacity of TCP under 503B FDA Outsourcing Guidelines. These potential investors may offer additional resources, but constraints imposed by an investment agreement with them may compromise the Company's capacity.
- With the addition of a first phase of automation using identified commercial-off-the-shelf small-scale sterile automation, capacity in the current Cary, NC facility is projected to support up to 35,000 sterile product scripts/month with approximately 40 shifts of operations per month.
- OneFul/TCP has been pre-qualified by SBP Office Owner, L.P., a joint venture between Starwood Capital and Trinity Capital Advisors for a new purpose-built pharmaceutical grade facility in Morrisville NC in the Southport Innovation Center, which can be readied for occupancy by September 2024, further expanding development and patient customer service operations.
- Certified analytical laboratory services provided by [ARL](https://www.arlok.com/) (<https://www.arlok.com/>) are substantial to support large volume production of GLP-1 type product quality assessment, have been a long-standing partner certified by FDA FEI 3003644883 – registered and inspected as an analytical (chemical and microbial analysis) laboratory. <https://www.arlok.com>
- A network of advisors and healthcare professionals who have worked for the companies previously continue to be actively engaged and available to support a major project with the Plan as needed.

• **Project Management:**

Our project methods include how the project will be developed, a proposed timeline of events, and reasons for why we suggest developing the project as described. We use formal and informal methods of project communication and management. Daily check-in of operating team members provides informal working communications. An administrative support lead keeps track of key milestones using Microsoft Project and online Monday project tools to initialize all known tasks, set schedule objectives, and track timelines weekly.

• **Proposed Project Schedule:**

The hypothetical example project chart below is based on concluding a binding contract with the Plan with a September 2024 project kickoff. The schedule will be updated upon receipt of a firm contract for the project.



## V. PROJECTED EXPENSES FOR PILOT PROGRAM

The following table is a non-binding budgetary estimate for the cost of a pilot program to support the Plan's goals as we perceive them from the basic outline embedded in this RFI. For a limited number of Plan members with a rapid startup plan timing, the following estimate for services and materials is offered to discuss a possible definitive contract.

Services – Category 1	Estimated Contract Bid
Program design and review with Plan administrators, Project management, and staffing to support Pilot goals	\$232,000.00
Collaborative development with 3 <sup>rd</sup> Party to configure, beta test, and implement a pilot Soft-PBM system supporting a limited number of member patients over a six to nine-month timeframe	\$390,000.00
Provide additional GP1-product stability test data for pilot and ongoing product shipment within North Carolina to improve logistics and achieve cost goals.	\$280,000.00
Identification of qualified brick-and-mortar partners for in-person member qualification, testing, and coaching for an initial pilot-level program	\$84,000.00
<b>Total Services Costs</b>	<b>\$986,000.00</b>
<b>Working Capital Support Category #2</b>	
Procure adequate GLP-1, GIP/GLP-1 API inventory to support the pilot program initially and ramp up to 10,000 patients/month by Q2 2025. Subject to pricing and sourcing negotiations, approximate, to be determined by the end Q4 2024	
Deliver Two (2) Units	\$ <b>440,000.00</b>
<b>Total Development Contract Budgetary Estimate (Non-binding – For Discussion Purposes Only)</b>	<b>\$1,426,000.00</b>

*Disclaimer: The prices in the preceding table estimate the services and product specifications discussed. This summary does not guarantee the final price. Estimates are subject to change if project specifications or costs for outsourced services change before a contract is executed.*

## VI. OPTIONAL FUNDING REQUEST:

### OneFul/TCP Funding Plans

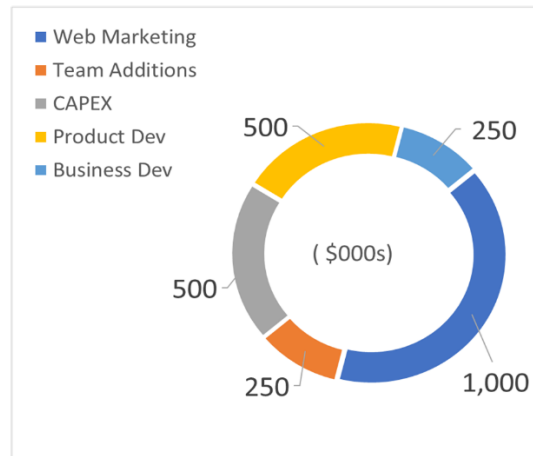
The following chart illustrates the financial plans of OneFul/TCP, which are critical for the Company to pursue investments in facilities infrastructure, capacity, and automation.

## Investment Goals

**Funds Raised to Date: \$7.1 M**

**Venture / Strategic – Q3 2024:  
Series A Preferred Shares  
\$5,000,000.**

**Supporting capacity additions and  
new product development and trials**



**Projected Use of Funds  
Q1 2024 thru Q1 2025**

OneFul receives significant development funding from the U.K. National Health Service Innovation-UK fund for its personalized cardiovascular polypill product and technology licensing from U.K. partners. This funding does not support work on GLP-1 and weight loss programs but supports overall technical and intellectual property development.

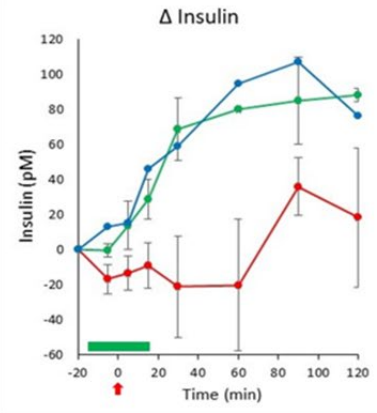
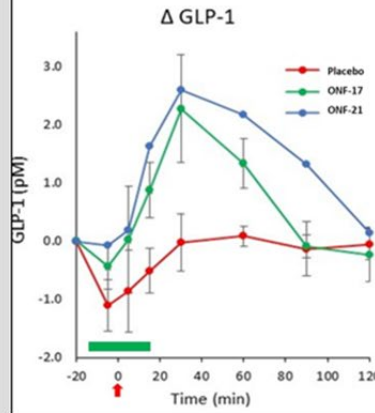
### GLP-OneFul Complementary Development Support

Additional funding is expected from the UK NHS and IDC to support the GLP-OneFul concept product to complement the injectable products currently offered. See the included whitepaper describing this relevant product development. The Company would like to have a dialogue with the State of North Carolina about other funding resources that may be available to support this work that is related to the Plan's interest and future desire for sustainable and affordable cardio-metabolic health support.

Specifically, the Company requests information about the [N.C. Innovation Fund](https://ncinnovation.org/) (<https://ncinnovation.org/>) as a source to fund observational trials of the GLP-OneFul product under the auspices of UNC Health researchers and a potential program for childhood obesity with the UNC Children's Research Institute. Information and guidance about other funding programs for small business enterprises that may support our developments and growth capital requirements may also underpin the Plan's goals.

## GLP-OneFul™ Concept Product Development:

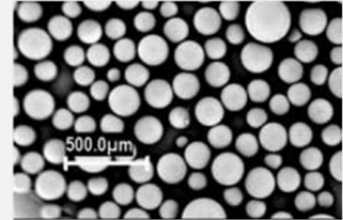
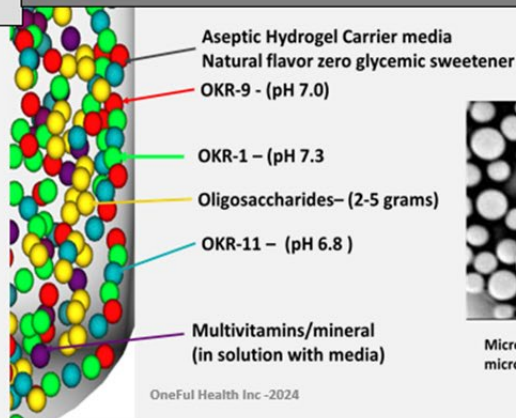
- Endogenous GLP-1 agonists
- Micro-encapsulated actives
- Oligosaccharides for microbiota
- Nutrients for general nutrition
- Minimal adverse side effects
- Post-semaglutide/terzepatide weight loss/ diabetes maintenance
- Obesity therapy in children potential first application



Active Ingredients micro-encapsulated and coated for sustained GLP-1, PYY release in distal colon for 8 to 12 hours



50-gram squeeze pouch, shelf stable, flavored



Microcapsules average diameter of 700 microns, 30-35% API loading

OneFul Health Inc -2024

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## APPENDIX OF SUPPORTING MATERIALS (FOLLOWING PAGES)

## **Better than GLP-1 Drugs: *Are Endogenous GLP-1 Medical Foods Possible?***

Edison Hudson, CEO, Founder [LinkedIn](#)  
OneFul Health Inc,  
Research Triangle Park, NC

According to Science, the 2023 Breakthrough of the Year was developing and adopting glucagon-like peptide-1 (GLP-1) agonists, branded as Wegovy, Zepbound, Mounjara, etc. The studies showing that these new long half-life injections produce 15 to 20% weight loss are impressive and good news. In November, a study of obese patients with cardiovascular complications using these products showed a 20% lower risk of heart attacks and strokes. An excellent summary of the potential health impact of these GLP-1 agonist drugs by the American Academy for the Advancement of Science is in this video. <https://youtu.be/QnmMSMF7wO4>

Holden Thorpe, editor-in-chief of Science, points out there are "More Questions Than Answers" (<https://www.science.org/doi/10.1126/science.adn3693>) about the promise of these drugs. The American College of Cardiology summarized the practical barriers to realizing these benefits, including prices over \$1,000 a month, poor insurance coverage, lack of physician familiarity, and shortages. A Journal of the American Medical Association report highlights how these drugs further exacerbate US healthcare inequality, as their benefits are mostly going to the well-heeled or insured, leaving out the very populations most affected by cardio-metabolic chronic disease.

Nevertheless, patient demand has gone viral, and the [GLP-1 agonist Drug Market is Exploding](#). Some are predicting that this drug class will become the Greatest of All Time.

[OneFul Health Inc.](#), is initially committing to this GLP-1 revolution by investing in bulk inventory of the FDA-approved form of semaglutide, the active ingredient of popular drugs Ozempic and Wegovy. Our accredited sterile pharmaceutical facility, [Triangle Compounding](#), is now filling patient prescriptions from our physician, clinic, and hospital providers with semaglutide and tirzepatide, and will support other supplies are tested.

OneFul possesses technologies that enable the delivery of high doses of active ingredients to specific regions of the digestive system. Using a patent pending method of micro-encapsulation, OneFul can capture active ingredients, including short-chain fatty acids ('SCFA's'), and some amino acids that have been shown in multiple research publications to stimulate GLP-1 and other satiety hormones, naturally.

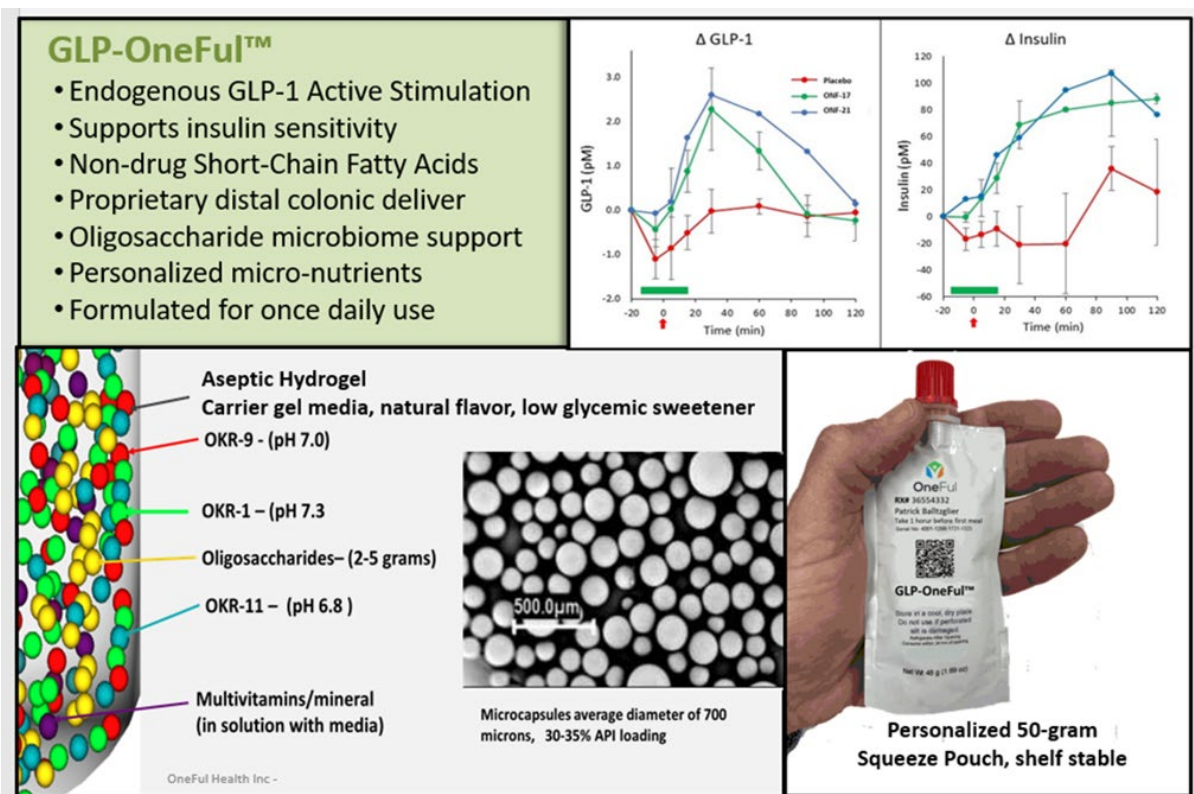


The research cited below, shows that when these acids are delivered to the distal colon in sufficient quantity, GLP-1 production by the L-cells that are prevalent there, naturally produce significant levels satiety hormones.

OneFul is also exploring the development of complementary treatments to the GLP-1 agonists drugs, based on recent GLP-1 incretin science. In November, OneFul completed the buy-back of [Panaceutics.com](http://Panaceutics.com)'s assets, a personalized nutrition and clinical foods supplier. Panaceutics has successfully scaled up the production of relevant formulations for microbiome support using OneFul's patented robotic personalization automation. In snack-sized (50-gram) squeeze pouches, these products have delivered multiple gram-level doses of active ingredients known to create small-chain fatty acids (SCFA). Several different SCFA stimulate significant levels of [endogenous GLP-1 in the human gut](#).

We have formulated and are planning to test this concept, which uses only FDA listed Generally Recognized as Safe ingredients, along with specialized oligosaccharide fibers that stimulate the microbiota of the gut, promoting higher insulin response and slowing food transits through the gut, reducing appetite.

OneFul conjectures that using its additive manufacturing platform to combine high doses of several SCFA promoting ingredients, along with other nutrients important to



the intestinal epithelial layer, might be able to produce the sustained release of natural GLP-1 and other satiety hormones. Over the past two decades, multiple animal and human research publications have pointed to the substantial stimulation of GLP-1 levels when ingredients that are generally recognized as safe (GRAS) are released for a sustained time in the correct segments of the intestines and colon. Other GRAS plant ingredients have been shown to suppress DPP-4 enzymes, which degrade the effects of GLP-1. Also well documented, even with the GLP-1 mimic drugs, is that many people respond differently, have different levels of adverse side effects, linked to the dosage levels of the treatment, and corresponding to age, sex, and diet, so likely making personalized treatment critical to effectiveness.

An evidence-based formulation and trial of personalized medical foods could be an approach that might lead to an effective, low-cost, and patient-centric treatment for diabetes (T2DM) and other metabolic diseases. Such complementary products may not be as powerful or have the long half-life of the injections, but they may assist those you have stopped the drugs and desire a long-term product that can help keep weight off, and glucose levels in better check. Products that are personalized, easy to integrate into daily life, and affordable would be ideal. Efficiently made-to-order with robotic automation, such products could be sold profitably at below "pumpkin-spice latte" prices. Medical foods prescribed to serve individual patients' metabolic and economic needs could answer many questions hindering the full healthcare value of the GLP-1 agonist breakthrough.

**Sources:**

- [Obesity meets its match \(science.org\)](https://www.sciencemag.org/obesity)
- [American College of Cardiology Summary Of GLP-1 Treatment Barriers](https://www.ahajournals.org/doi/full/10.1161/aha.116.312111)
- [Racial, Ethnic, and Socioeconomic Inequities in Glucagon-Like Peptide-1 Receptor Agonist Use Among Patients With Diabetes in the US](https://www.diabetesresearchjournal.com/2017/05/15/racial-ethnic-and-socioeconomic-inequities-in-glucagon-like-peptide-1-receptor-agonist-use-among-patients-with-diabetes-in-the-us/)
- [GLP-1 agonist Drug Market is Exploding](https://www.fiercebiotech.com/analysis/1000000000)
- [Short-Chain Fatty-Acid-Producing Bacteria: Key Components of the Human Gut Microbiota](https://www.nature.com/articles/nrn20170515)
- [Exploratory clinical studies of GRAS compounds in Type 2 diabetes patients, conducted at Carolina Research, gastrointestinal research clinic in Greenville, NC](https://www.gastrojournal.org/doi/full/10.1053/j.gastro.2017.05.011)
- [Functional foods-based diet as a novel dietary approach for management of type 2 diabetes and its complications](https://www.mdpi.com/2077-0383/8/11/1911)
- [Mechanisms to Elevate Endogenous GLP-1 Beyond Injectable GLP-1 Analogs and Metabolic Surgery](https://www.sciencedirect.com/science/article/pii/S0014714517330000)
- [Gut Microbial Signatures for Glycemic Responses of GLP-1 Receptor Agonists in Type 2 Diabetic Patients: A Pilot Study](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5611111/)

# The History and Current Burden of **Medically Managed Weight Loss**



While modern sedentary lifestyles and heavily processed diets have certainly contributed to **74% of Americans being overweight or obese**, weight management has always posed a global challenge.<sup>1</sup> Maintaining a normal weight is paramount to living a healthy, happy, and productive life as overweight and obesity are greatly associated with the leading causes of death - heart disease, stroke, and diabetes.<sup>2</sup>



Medications for weight management have a long history. In the 18th century, people relied on soaps and vinegars as forms of purgatives. In the late 19th and early to mid-20th century, doctors began prescribing thyroid hormones, dinitrophenol, and amphetamines for weight loss until the side effects became apparent.<sup>3</sup>

Following that, derivatives of amphetamines such as phentermine and other serotonergic drugs and monoamine reuptake inhibitors were prescribed for weight-loss in the 1950s.<sup>4</sup> All of these drugs were tested and approved by the FDA in 1973, meaning they were not approved using the modern safety standards that we employ when studying pharmaceuticals today.<sup>5</sup>

After patients experienced limited weight loss and severe adverse effects from these medications, the American Association of Clinical Endocrinologists and the American College of Endocrinology stated that lifestyle modification - consisting of a reduced-calorie diet and increased physical activity - is the most effective and healthiest strategy for weight management.<sup>6</sup>

Despite lifestyle behaviors having the greatest impact on one's weight, pharmaceutical companies continued formulating and developing weight management drugs, with the FDA approving the first drug for weight management in 2021 since 2014.<sup>7</sup>

# The Challenges with **Medically Managed Weight Loss Programs**

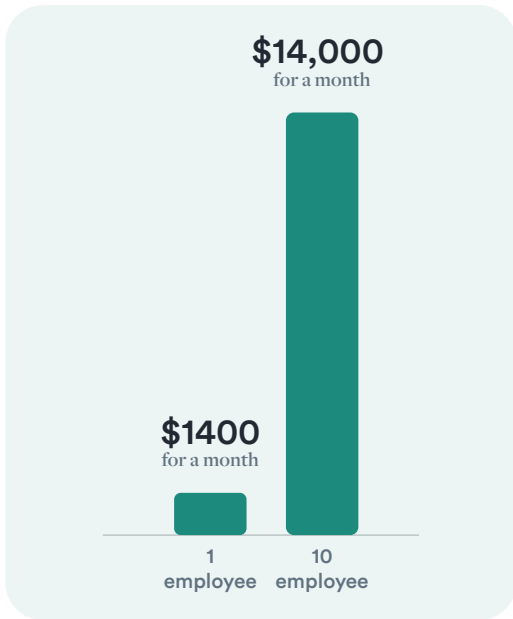
## Cost

According to a study from Kaiser Family Foundation, *employer-based health plans cover 42% of all prescription drugs*<sup>8</sup>. Pharmaceuticals are the number one expense for employers, and that expense positively correlates to the cost of the drug.

Furthermore, Kaiser Family Foundation found that a small number of drugs account for a disproportionate amount of total drug costs<sup>9</sup>. In fact, the top 5 most expensive drugs account for at least 10% of total prescription drug spending amongst employers.<sup>10</sup>

Source : [3]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[4]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[5]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[6]<https://pro.aace.com/disease-state-resources/nutrition-and-obesity>

[7]<https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
[8]<https://www.kff.org/medicare/press-release/https-www-kff-org-medicare-press-release-new-analysis-compares-prescription-drug-spending-and-use-across-large-employer-plans-medicare-and-medicaid/>  
[9]<https://www.benefitspro.com/2019/05/21/10-drugs-topping-employers-plans-pharma-spend/>  
[10]<https://www.benefitspro.com/2019/05/21/10-drugs-topping-employers-plans-pharma-spend/>



*Average cost of GLP-1 drugs*

*The 2020 National Health Expenditures revealed that employer health expenditures grew in 2020 at the fastest rate of growth since 2002.<sup>[1]</sup>*

Should these weight-loss drugs become widespread amongst employees, employers will be faced with covering extremely expensive GLP-1 drugs that average about \$1400 (depending on which drug) for a month's supply of weekly injections. If an employer now has to cover 10 employees GLP-1 medications, that costs them an extra \$14,000 a month on just ten employees.

## Care

Even worse, out of those ten employees, not all will see results, and those who do, will have to make serious lifestyle changes to see continued results.

Ultimately, these GLP-1 medications add yet another medication into *overflowing pill cabinets and fail to address the root cause of obesity*. Instead, employers should focus on empowering their employees with the knowledge to create positive lifestyle change that moves beyond managing symptoms and actually targets the root cause.

“

*Patients still need to eat healthily, work out, and keep in touch with a professional who can monitor their progress and tweak their program. The U.S. medical system isn't exactly set up for that kind of personalized medicine, and doctors aren't immune from biases about weight gain.”<sup>[2]</sup>*

**Ethan Lazarus**

Obesity Medicine Association President

Source : [1]<https://www.cms.gov/newsroom/press-releases/national-health-spending-2020-increases-due-impact-covid-19-pandemic>  
 [2]<https://www.bloomberg.com/news/features/2022-01-04/prescription-weight-loss-drugs-for-obesity-work-if-your-doctor-lets-you-get-them>



# A Sustainable Solution to America’s Obesity Epidemic: **Incorporating Genetics and Gut Microbiome to Personalize Weight Care**

Digbi Health — a caring and innovative personalized digital therapeutics company — harnesses gut microbiome, genetics, and digital care to treat the root cause of obesity and empower members with knowledge to sustainably lose weight without the aid of a lab-made pharmaceutical.

When employers sign up with Digbi, each employee submits an *oral swab and fecal sample along with demographic and lifestyle information*. Using test results and AI predictive modeling, Digbi suggests each employee make small but impactful changes to their personalized food and lifestyle, ultimately reducing or reversing their symptoms. Digbi also provides 1:1 coaching, digital content, and a vibrant member support community.

By using food as medicine, Digbi’s coaches teach each members what foods are best for their body and why based on their unique gut and DNA.



*No two people have the same genetic and gut microbiome make-up, so no two people should receive the same recommendations.*

**Ranjan Sinha**  
CEO and Founder of Digbi Health

75% of Digbi members have lost weight through our program, and over 30,000 pounds have been lost collectively amongst our members over 3 years. *By treating the root cause of obesity - the gut microbiome - members also report improvements in*



**89%**

Digestive Disorder Symptoms

**75%**

Insomnia/Sleep Disorders

**66%**

Depression/Anxiety

**66%**

Chronic Inflammatory Pain

**50%<sup>13</sup>**

chronic acne/eczema

*Empower your employees to take greater control of their health destiny by helping them address the root cause of their obesity.*

## To learn more information

Contact Us  
at [hello@digbihealth.com](mailto:hello@digbihealth.com)



# An Overview of **Weight Loss Medications**

There are currently five medications currently approved by the FDA for chronic weight management. Two of them are approved for long-term use, and the other three are approved for short-term use (less than 12 weeks). While they all work differently and have different side effects, all five categories share one thing in common: they must be used in addition to a reduced calorie diet and increased physical activity.<sup>14</sup>



## **Wegovy / Semaglutide**

In June 2021, The FDA approved Wegovy - *an injection approved for chronic weight management in adults* who are obese or overweight with at least one weight-related chronic condition. Wegovy works by mimicking a hormone called glucagon-like peptide-1 (GLP-1), and they increase satiety and have a regulatory effect on glucose homeostasis through the reduction of blood glucose levels and insulin release.<sup>15</sup> It is a higher dose version of the diabetes drug Ozempic, which

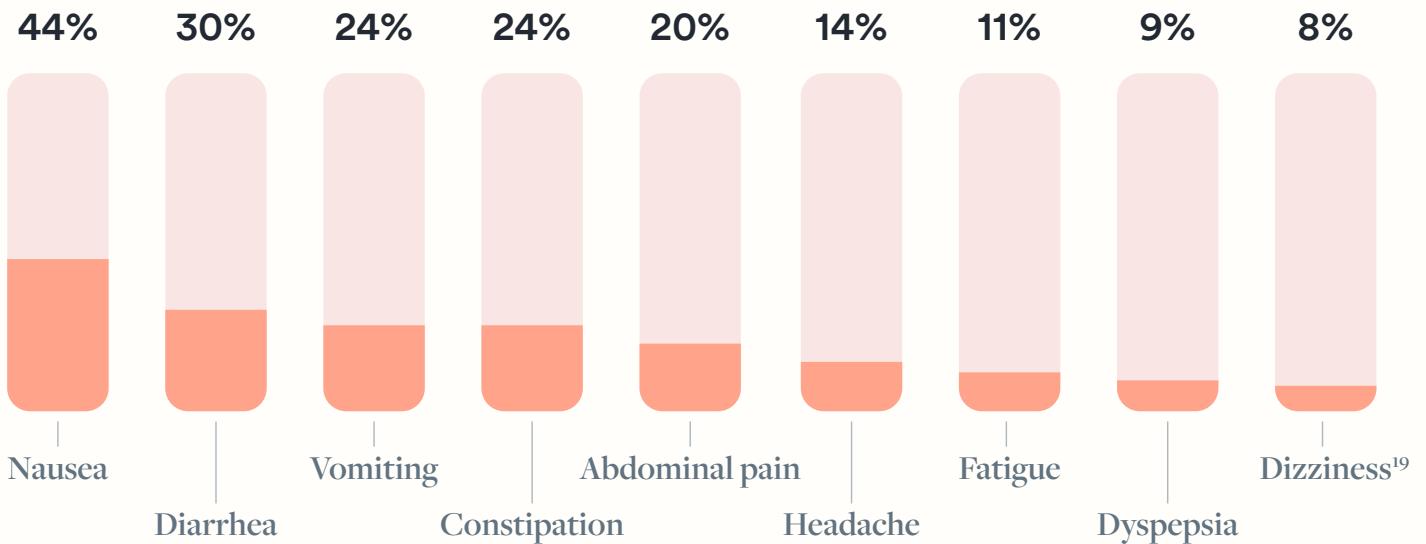
Source : [13]<https://news.blueshieldca.com/2020/07/15/more-than-23-500-blue-shield-of-california-members-reclaim-their-health-in-first-year-of-reimagined-wellvolution-program>  
[14]<https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
[15] <https://pubmed.ncbi.nlm.nih.gov/2726901/>



continues the trend of manufacturers repurposing diabetes drugs for other conditions common in diabetic patients.<sup>16</sup> Wegovy must be dosed one a week long-term.

Wegovy was approved by the FDA after four 68-week trials.<sup>17</sup> 33% of the patients lost more than 20% of their body weight during the 68 weeks, with the average being 15% body weight loss.<sup>18</sup> Compared to the other four categories of weight loss drugs, Wegovy resulted in the greatest weight loss.

### Wegovy causes many *adverse side effects*:



### Saxenda

The second most common weight loss medication is Saxenda. Like Wegovy, it is also a GLP-1 antagonist involved in the regulation of energy balance and activation to reduce food intake and thus body weight<sup>20</sup>. In other words, Saxenda is a synthetic version of a satiety hormone that makes you feel full.

Similar to Wegovy, Saxenda injections must be administered weekly (long-term), with an *average monthly cost of \$1,300 without insurance*.<sup>21</sup> Though slightly less promising than Wegovy, Saxenda still produces a 9% body weight loss, which contributes to about 17-18 lbs after 1 year.<sup>22</sup>

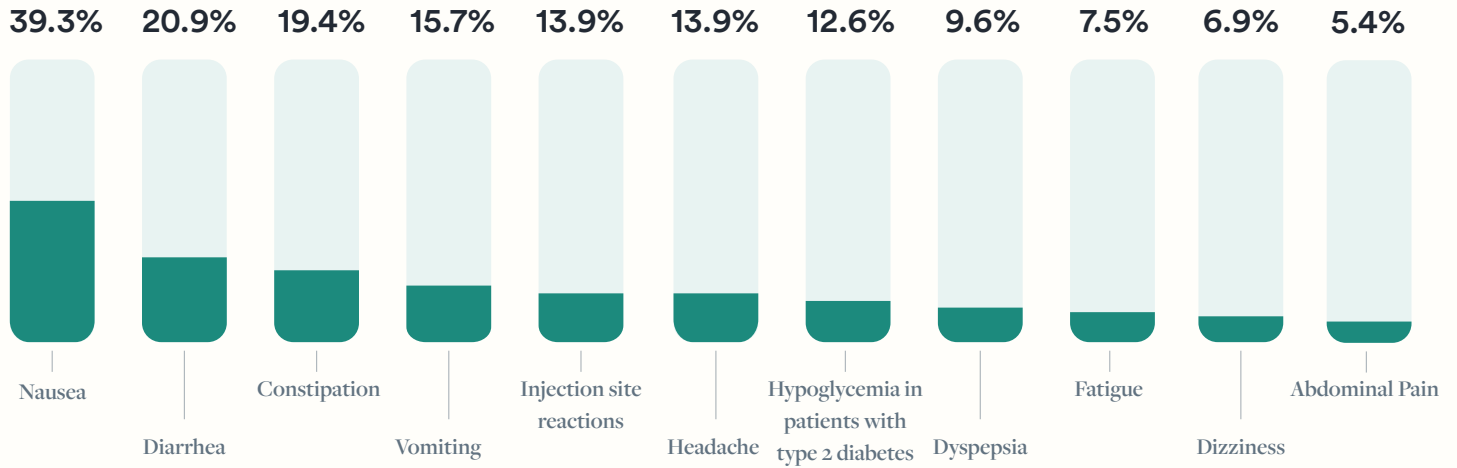
Source : [16]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
 [17]<https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014>  
 [18]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
 [19]<https://www.drugtopics.com/view/a-review-of-fda-approved-medications-for-chronic-weight-management>

[20]<https://pubmed.ncbi.nlm.nih.gov/2726901/>  
 [21]<https://www.forbes.com/sites/joshuacohen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
 [22]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>





Of the people using Saxenda, these percentages *experienced the following adverse effects:*



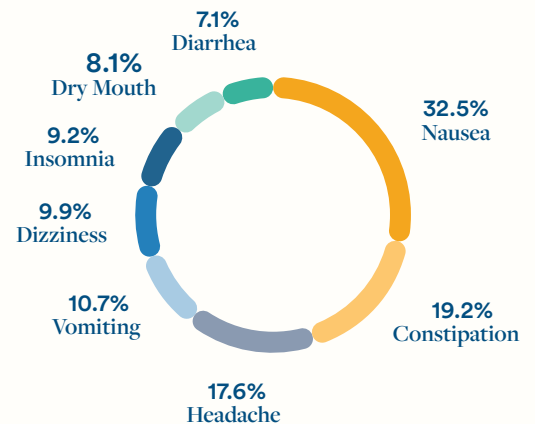
### Naltrexone ER / Bupropion ER (Contrave)

The third weight loss medication approved by the FDA is Naltrexone ER / Bupropion ER (Contrave). Naltrexone is an opioid antagonist, and bupropion is a dopamine and norepinephrine reuptake inhibitor. Before approved for a weight loss drug, *bupropion was approved for depression and smoking cessation*<sup>23</sup>. Bupropion reduces appetite through adrenergic and dopaminergic pathways in the hypothalamus.

Bupropion is only approved for short-term use (less than 12 weeks). Compared to the two Semulgitide’s previously mentioned, Bupropion is less effective, causing lower rates of weight loss.

*Bupropion is incredibly dangerous in patients with hypertension as it increases blood pressure. It also has the following negative side effects:*

The box also warns it can increase suicidal thoughts and behaviors.<sup>24</sup>



Source : [23]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
[24]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>

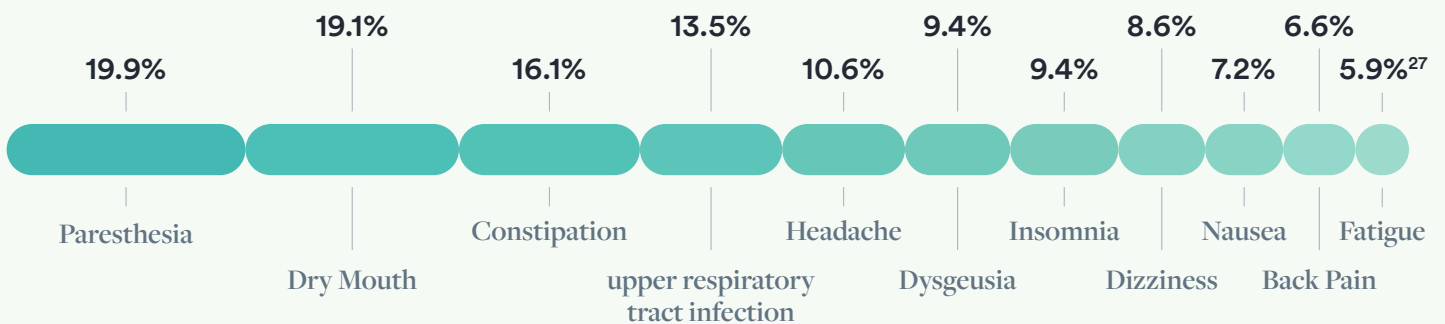


## Phentermine / Topiramate ER (Qysmia)

Phentermine was approved for short-term use by the FDA in 1959, but is still a commonly prescribed anti-obesity medication.<sup>25</sup> It is a derivative of amphetamine, meaning it's a controlled substance and stimulant. Phentermine works by releasing catecholamines in the hypothalamus which decreases appetite and food intake, thus enhancing satiety<sup>26</sup>.



*Like all the other weight loss medications previously mentioned, Qysmia also has adverse side effects:*



Source : [25]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>  
 [26]<https://www.forbes.com/sites/joshuachen/2021/06/05/obesity-drug-wegovy-holds-promise-but-faces-reimbursement-challenges/?sh=1725e64a4bd5>  
 [27]<https://www.atlantaendocrine.com/blog/comparing-anti-obesity-medications>

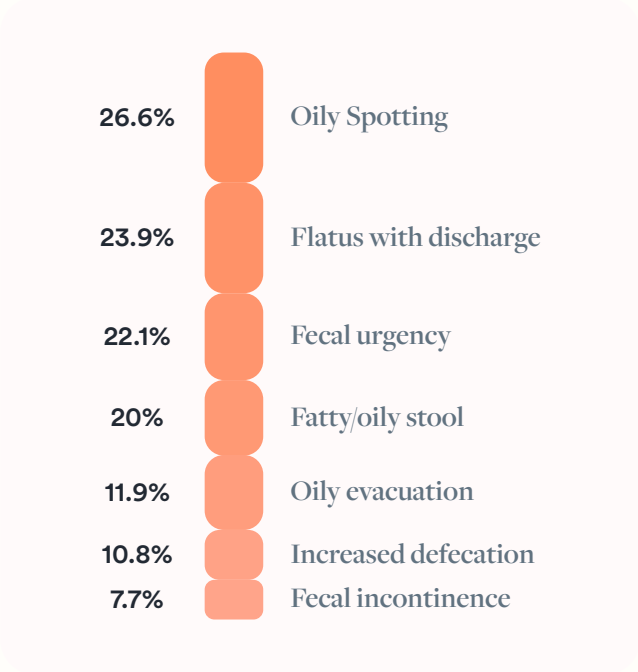



## Orlistat

Orlistat is the only chronic weight management medication available both over the counter and by prescription. Orlistat works by inhibiting gastrointestinal lipases, which results in decreased fat absorption. Patients on Orlistat must adhere to a reduced calorie diet that contains about 30% of the calories from fat.

*Even though Orlistat can be purchased OTC, **it still comes with a host of side effects:***

*Other warnings: decreased absorption of fat-soluble vitamins, severe liver injury, increased GI pain in people with high fat diet, warning for organ transplant as it interacts with immunosuppressants.*



# REFERENCE



June 6, 2024

Re: RFI Number: 270-20240419GLP, NC State Health Plan for Teachers and State Employees, OneFul Health Inc.

Dear Secretary Folwell and others administering the State Health Plan:

Thank you for your efforts on behalf of the people of the state of North Carolina. I am writing to you as a diabetes/obesity physician, researcher, and customer in support of the OneFul Health proposal to provide semaglutide and tirzepatide to the State Health Plan.

First, my background. I came to the University of North Carolina School of Medicine in July 1994 to start a diabetes center to provide clinical care, research, and training. I am especially proud of the impact our program has had on training an entire generation of providers in NC. We have provided excellent care for tens of thousands of patients with diabetes. We have also been centrally involved in the development of the GLP-1 receptor agonist (GLP-1RA) class of drugs since 1997 for both diabetes and weight management indications. UNC was the site of the first study of GLP-1RA in patients with diabetes way back in 1998.

I have been a consultant and investigator for all the companies that develop GLP-1RA. I am a former president of the American Diabetes Association and have received national awards from them for my success as a researcher in 2019 and as a clinician this year. Having worked in the GLP-1RA field for more than 20 years and as someone with a BMI of 32 with associated problems (hypertension, dyslipidemia, elevated liver enzymes, insulin resistance), I asked my primary care doctor to prescribe Wegovy as soon as it was FDA approved. I lost sixty pounds and all my metabolic problems resolved. My BMI is now twenty-two.

The GLP-1RA have the promise to revolutionize care of people with obesity who face terrible health outcomes, early death/disability, stigma, and psychological burden. They have been shown to not only reduce weight but reduce cardiovascular events in high-risk patients. The concern you have raised about their cost is completely appropriate. Their value is great, but cost effectiveness analysis is driven by cost. A number of studies suggest that at a cost of \$200-\$400 a month, semaglutide for instance would be cost effective for managing people with overweight/obesity and established metabolic disease (stage 2) as conceived of by the American Heart Association in 2023.

But what I really want to tell you is that when the SHP stopped paying for my Wegovy and with the difficulty in getting Wegovy or Zepbound at any cost, I did my due diligence about the compounding pharmacy marketplace. Through my primary care doctor, I became aware of OneFul and the Triangle Compounding Pharmacy in Cary. I have been taking tirzepatide 7.5 mg a week since April 29. My weight and metabolic parameters have held steady. Their service is outstanding. As perhaps one of the best-informed consumers and prescribers of GLP-1RA on the planet, I give them my strong endorsement. I understand that they have made a proposal to you. (Though I have lots of conflicts of interest with the pharma industry, I have none with OneFul.)

If I can help with your deliberations, please feel free to reach out. Best wishes for a successful negotiation to get GLP-1RA for weight management to our State Health Plan members at a cost-effective price. Again, thank you.

Sincerely,

A handwritten signature in black ink that reads "Buse". The signature is written in a cursive style and is positioned above the printed name.

John B. Buse, MD, PhD  
Verne S. Caviness Distinguished Professor  
Director, Diabetes Care Center  
Director, NC Translational and Clinical Sciences Institute

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