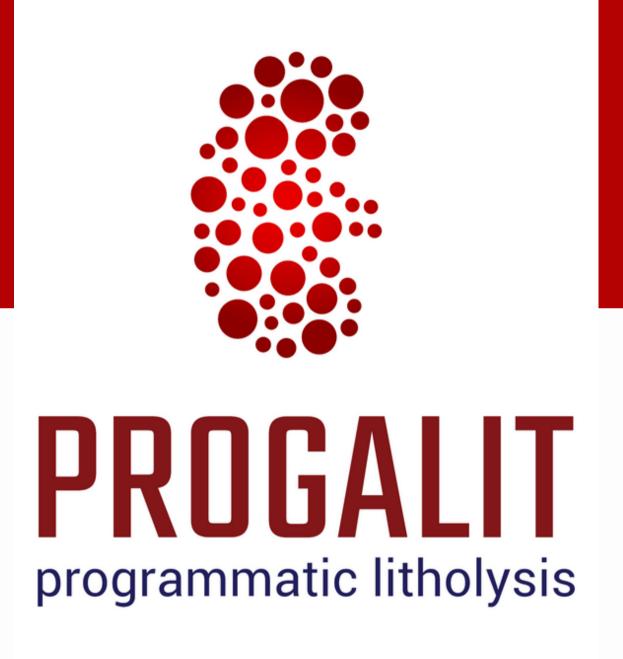




Software as a Medical Device (SaMD). Automation of treatment and prevention of urolithiasis.



Developed and tested in Ukraine by "Programmatic Litholysis" LLC, 2023



Information for investors

- The healthcare landscape is undergoing a digital revolution, driven by the increasing adoption of Al in diagnostics and patient management. This presents a groundbreaking opportunity in the Software as a Medical Device (SaMD) market, particularly for applications targeting kidney stone treatment.
- Here's why investing in our SaMD solution for kidney stones is compelling:
- Market Growth: Al-powered diagnostics and patient management are poised for exponential growth, fueled by rising demand for personalized and efficient healthcare.
- Sustainable Business Model: SaMD solutions benefit from insurance coverage, creating a reliable revenue stream and long-term financial stability.
- High Investment Return Potential: Early entry into this rapidly expanding market offers significant potential for high returns on investment.
- Addressing a Critical Need: Kidney stones are a prevalent and costly healthcare issue. Our solution effectively addresses this unmet need, improving patient outcomes and reducing healthcare burdens.
- By investing in our SaMD solution, you're not just backing innovation, you're contributing to a healthier future for millions suffering from kidney stones. Join us in revolutionizing healthcare and unlocking the immense potential of the SaMD market.

Annual market volume in the world as of 2023



Market growth of 6-7% until 2030

The SaMD market and the market for the treatment of urolithiasis are two growing markets that have high potential for investment.

Progalit is a solution that connects these two markets.

Total Available Market (TAM)

\$ 3.2 Billion > \$4.5 2030

The world market of SaMD - \$ 1.4 billion
The global market for the treatment of KSD is \$1.8 billion

Serviceable Available Market (SAM)

\$ 400 Million > \$560 Million 2030The market of specialized SaMD - \$ 300 million The market of treatment of urate

Serviceable Obtainable Market (SOM)

\$ 200-350 Million

stones - 100 million

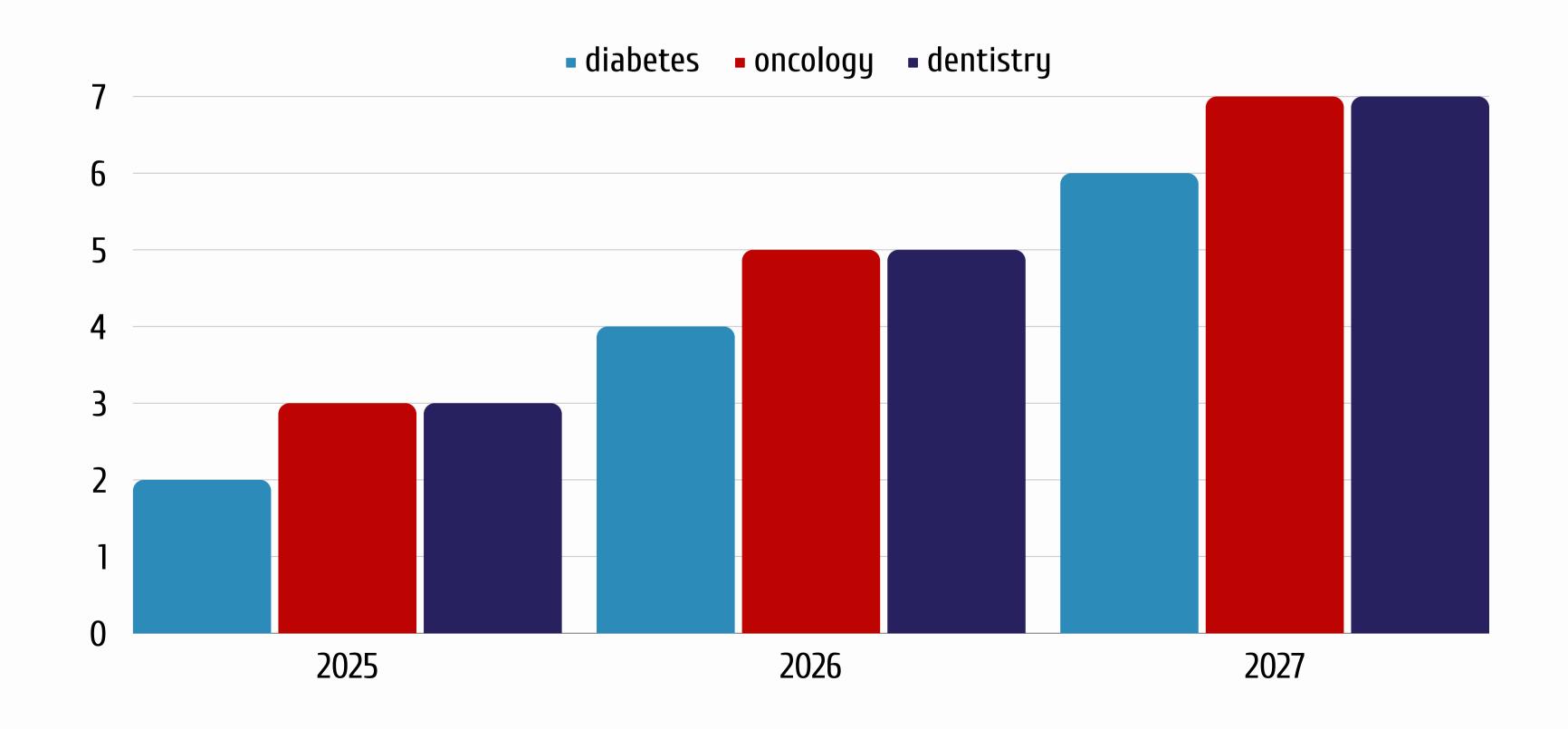
Market of Europe and the USA for the treatment o urate stones.

The target financial indicator after 3 years is \$150 million, 60% of SOM

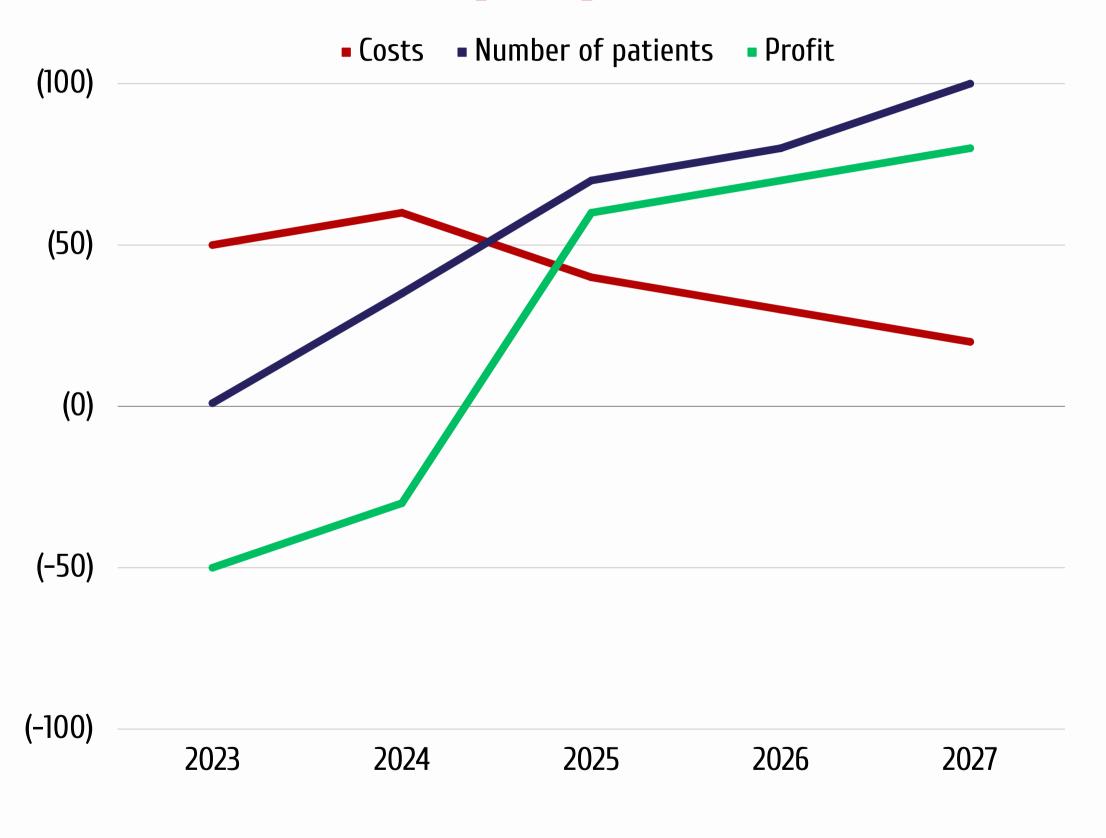


Our goal is to be the market leader in Europe and the USA for pH correction services for the treatment and prevention of diseases in which pH correction is indicated for treatment, primarily urolithiasis, as well as renal complications in rheumatology.

The development potential of our services after the first year on the market – services in the treatment of diabetes, oncology, cosmetology and dentistry – access to the market with a turnover of \$10+ Bln.



Company Traction Plan 2024-2027 pp



Costs

-30%

In the next 4 years, development and support costs will decrease by 30% in the overall budget structure. Cost reduction will be achieved through the introduction of new technologies and automation of development methods.

Number of patients +35% per year

The planned increase in the number of patients is +35% per year. With the number of patients in treatment and prevention 200,000 in 2027.

Profit +30% per year The planned profit indicator is +30% per year in the budget structure. With a planned rate of 75% in 2027.

Business Model: B2B2C

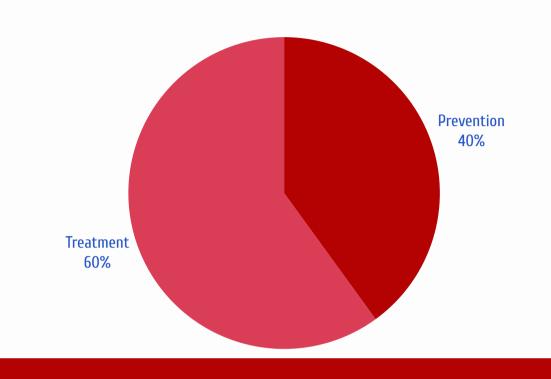


PROGALIT SaMD software is sold or licensed to medical institutions (B2B). Medical institutions, in turn, offer the program to their patients (B2C). Patients can pay for the program using their insurance policy or their own funds.

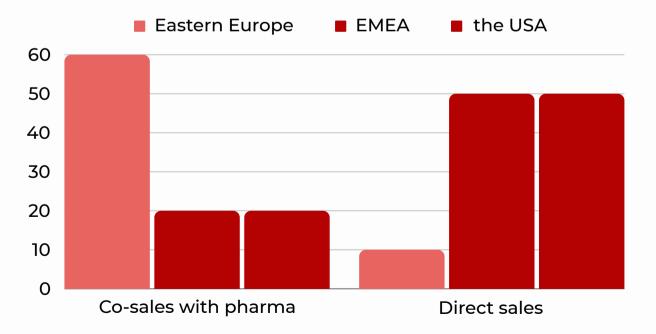
Payment through a patient's insurance policy is the most common way to monetize SaMD. In this model, the medical facility receives reimbursement from the insurance company for services provided to the patient.

Proportion of patients who will pay for treatment and prevention: 60% of patients will pay for treatment with SaMD and 40% for prevention.

The ratio of treatment and prevention

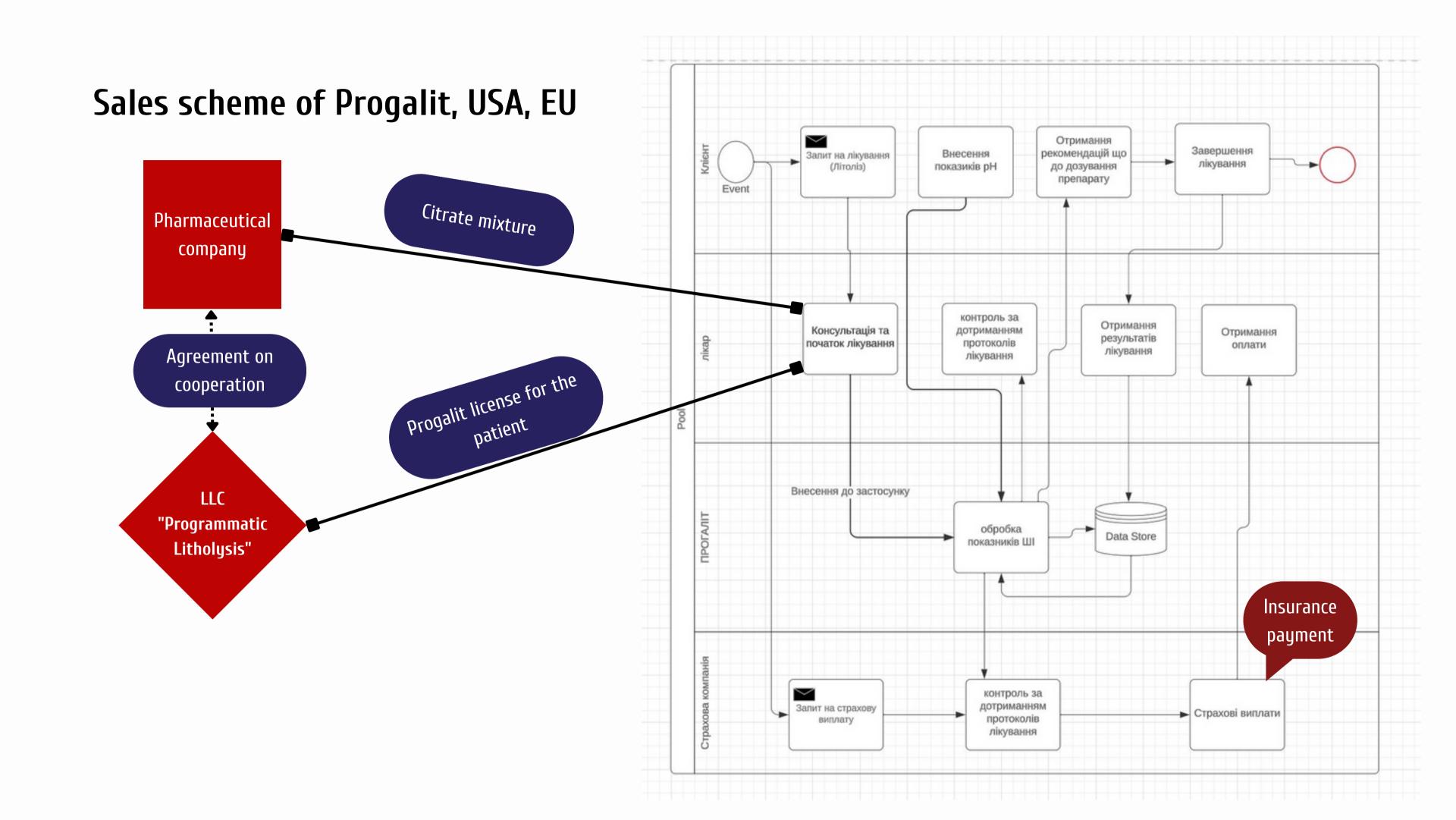


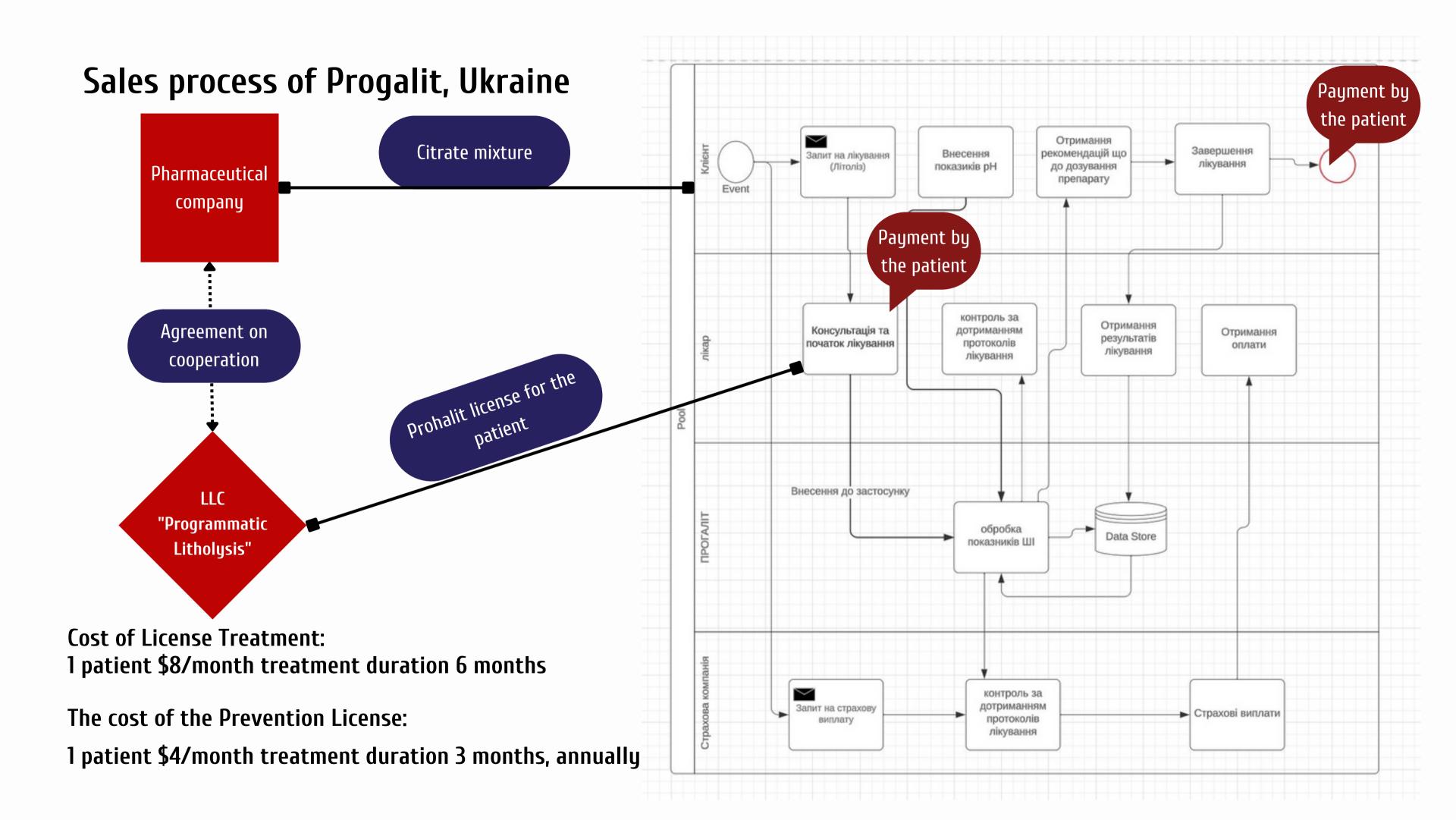
Sales structure



Progalit license types

Type of eLicense	Clinic	Doctors	Patient	Insurance Company
Treatment	anv	nny		
Prevention	anv	ans	anv	ans





Development strategy



2023: Investment - \$150,000



June 2025: Investment - \$3,000,000

Start of sale of Progalit in Ukraine Patients in Progalit at the end of the year 50 people

Development in the USA and the EU Patients in Progalit in May - 20,000 people

2024, May: Investment - \$550,000

Registration in the USA, EU
Patients in Progalit in May - 1000 people, in
December - 4000 people

January 2026: Sales (pharma, IT digital health) \$70-100 million

Patients in Progalit 50,000 people Sale of Prohalit as SaMD in USA, EU.

Estimate

Articles of Expenses	1 month	2 months	3 months	4 months	Total start	May 2024	2025 June	January 2026
Creation of a verisya 1.0 software product for use in Ukraine: mobile application and chat bot in TG.	\$22,500	\$22,500			\$45,000	\$40,500	\$76,950	\$38,475
Registration in Ukraine		\$6,000			\$6,000			
Registration in the USA, EU						\$400,000		
Work support: server, security, certification	\$2,000	\$2,000	\$2,000	\$2,000	\$8,000	\$8,000	\$9,600	\$9,600
Product Marketing:			\$20,000	\$20,000	\$40,000	\$80,000	\$320,000	\$384,000
Labor fund:								
CE0	\$6,000	\$6,000	\$6,000	\$6,000	\$24,000	\$24,000	\$175,200	\$175,200
Project manager	\$3,000	\$3,000	\$3,000	\$3,000	\$12,000	\$12,000	\$108,000	\$162,000
Office (accountant, lawyer)	\$3,000	\$3,000	\$3,000	\$3,000	\$12,000	\$12,000	\$72,000	\$93,600
Work of the supervisory board: 6 times a year					\$6,000	\$24,000	\$700,000	\$1,400,000
Total expenses:	\$36,500	\$42,500	\$34,000	\$34,000	\$147,000	\$600,500	\$1,461,750	\$2,262,875
Number of patients	100	500	900	1500	1500	4500	19350	50310
Sales proceeds	\$3,400	\$17,000	\$30,600	\$51,000	\$102,000	\$765,000	\$3,947,400	\$10,263,240

Estimate Ukraine, EU and US

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The founders of the start-up



Oleg Vustenko, CEO

Doctor, MSc, EMBA; 15 years of clinical research management; 40 countries, 27 projects.



Oleksandr Leikin, CTO

IT architect;

Inventor;

Author of more than 20 patents.



Dmytro Solopov, CMO

Urologist;

Inventor;

IT developer - CMO.

Co-owners



Olena Mazura - CFO

Finance and marketing;
28 years of foreign economic activity;
18 years of business consulting and training;
16 years of cooperation with medical and diagnostic centers;
Co-founder of Al start-ups.



Serhii Oprya - CVO

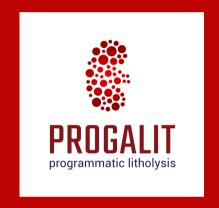
LLC "Mars", TV group "Inter";
26 years of managerial work;
18 years of business consulting;
14 years of marketing and sales experience;
8 years in HR;
5 years of mentoring, consulting of startups;



Tatyana Godyak - CBDO

8 years of management experience;
Foreign economic activity;
International management;
Entrepreneur;
Occupational health and safety

expert.



Thank you for your attention to the problems of treating urolithiasis

"Programmatic Litholysis" LLC is a med tech company that develops solutions for the treatment of diseases related to the regulation of the pH level.

Our team consists of experts from various fields: medicine, clinical research, IT, finance, project management and entrepreneurship.

Our technology has the potential to change the lives of people suffering from diseases related to pH imbalances in the body.

We are working on the development of innovative technologies that will help people around the world lead healthy and fulfilling lives.

Here are some of our key achievements:

- We have developed a unique technology that allows you to precisely control the pH level in the body and dissolve urate stones in the kidneys
- We conducted a successful beta test involving more than 30 patients, which proved the effectiveness of our technology.
- We are currently seeking investment from leading investors in the MedTech sector

PROGALIT programmatic litholysis

Learn more about us on our website at progalit.com

The urolithiasis is a problem

- Uric acid stones form when the pH of urine falls below 5.5;
- When we raise the urine pH above 6.5 and maintain it, with the help of medication (citrate mixture) and/or diet, we can dissolve uric acid-urate stones, this is called **litholysis**;
- Regulation of pH by the method of **litholysis** requires a lot of time and effort on the part of the doctor and the patient.

Patients

About 5-10% of the global population suffers during their lifetime, with a recurrence rate of 50% within 10 years and 75% within 20 years.

Factors that influence

CSH is associated with age, gender, geography, climate, race, diet, genetic factors, and other diseases – requiring individual treatment on a patient-by-patient basis.



SOLUTION



PROGALIT - "programmatic litholysis"

Software as Medical Device - SaMD A medical program with artificial intelligence that regulates the process of medicinal litholysis to dissolve uric acid stones in the kidneys by correcting the pH level.

Patented treatment method Registered Trademark

Market

Analysis

Software as Medical Device growth from \$1.4 billion in 2021 to \$10.4 billion in 2028, CAGR -38.4%

Information is also available in the public domain and professional market research by The insight Partners, Business Research Insight, Fortune business Insights

Area

Medicine, urology.

The volume of the market for the treatment of urate stones is \$100 million.

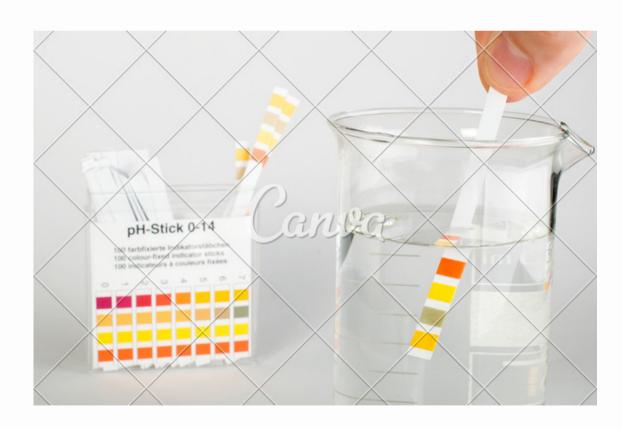
Total market volume \$1.47 billion (2019) - \$2.21 billion (2027) CAGR - 21.9%

Added layer

A complex solution combining medicine, pharmaceutical industry, IT, Artificial Intelligence and nutrition, Improves the efficiency of litholysis

LITHOLYSIS

A tool for measuring the pH of urine (device, test strip)



Medication - citrate mixture



PROGRAMMATIC LITHOLYSIS is a method of treatment

CRM system for doctors

Algorithms with Al support

Multi-channel interface for patients







A tool for measuring the pH of urine (electronic tester)

Medication - citrate mixture





PROGALIT SaMD program as a medical device

CRM system for doctors

Algorithms with Al support

Multi-channel interface for patients











Automation of outpatient treatment and prevention of urolithiasis

Indirect competitors, SaMD

Name SaMD			Area of Medicine	Financial information is available			
	Monitoring and alerts	Screening and diagnosis:	Treatment of diseases	Treatment	Improving compliance to treatment		
S3 connected devices	So	So	So	So	So	Chronic and rare diseases	\$67 million, revenue 2022
Dexcom	So	So	So	So	So	Diabetes	\$970 million, revenue 30 2023
Medisafe	So	No	So	No	So	Oncology	\$30 million investment, round C, 2021
BrightInsight	So	So	So	So	So	Cardiology, Oncology and other chronic diseases	\$166 million investment, 3 rounds, 2021
lt's progal	So	So	So	So	So	Urology	

Direct competitors, SaMD in Urology

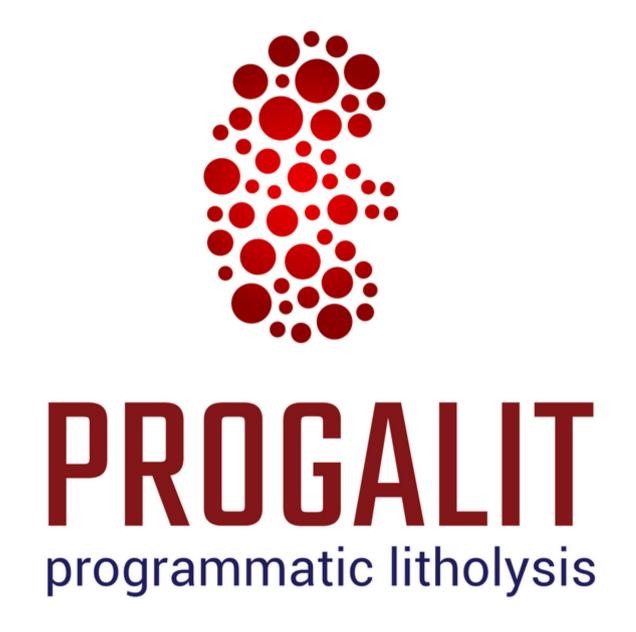
Name SaMD		Available information				
	Monitoring and alerts	Screening and diagnosis:	Treatment of diseases	Treatme nt:	Improvement of compliance to treatment, diet	
MD Stone	So	No	No	So	No	No SaMD status, 5k+ downloads
Kidney STONE Score Calculator	No	So	No	No	No	Does not have SaMD status
Kidney Stone Scoring	No	No	So	No	No	Does not have SaMD status
My Kidneye, My Health	No	No	No	No	So	No SaMD status, 1k+ downloads
lt is progal	So	So	So	So	So	SaMD status

Competitive Advantages of Progalit

SaMD status	 Subscription as monetization using insurance coverage in a market with ever-increasing demand for treatment Payment for the doctor's services provided through the digital service is a new revenue channel for medical institutions 				
Functional	Automation of outpatient treatment and prevention				
A niche product with great potential	Digitization of treatment in surgery related area of medicine				
Regulation of one of the parameters of human homeostasis – pH	Scaling of the service in other fields of medicine: diabetes, rheumatology. oncology				

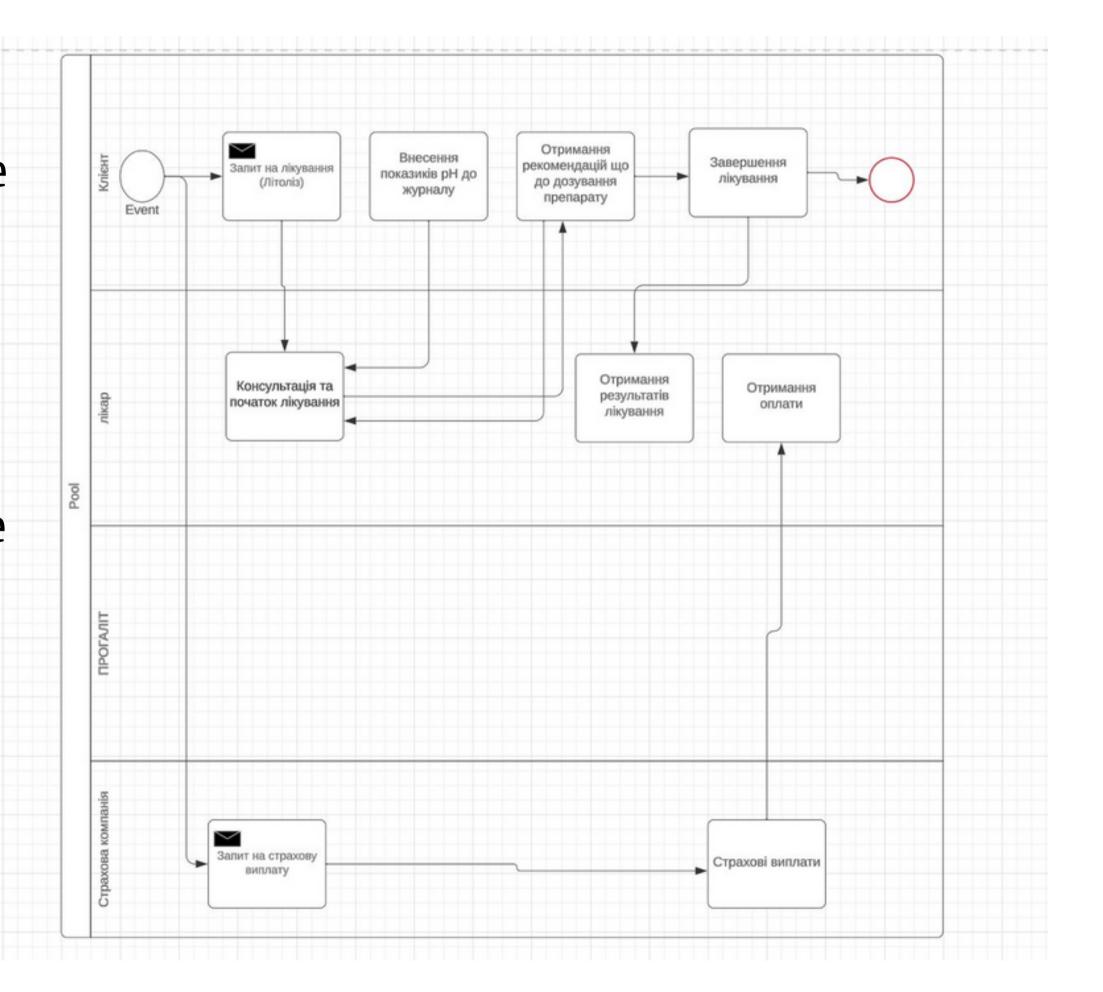


Additional materials



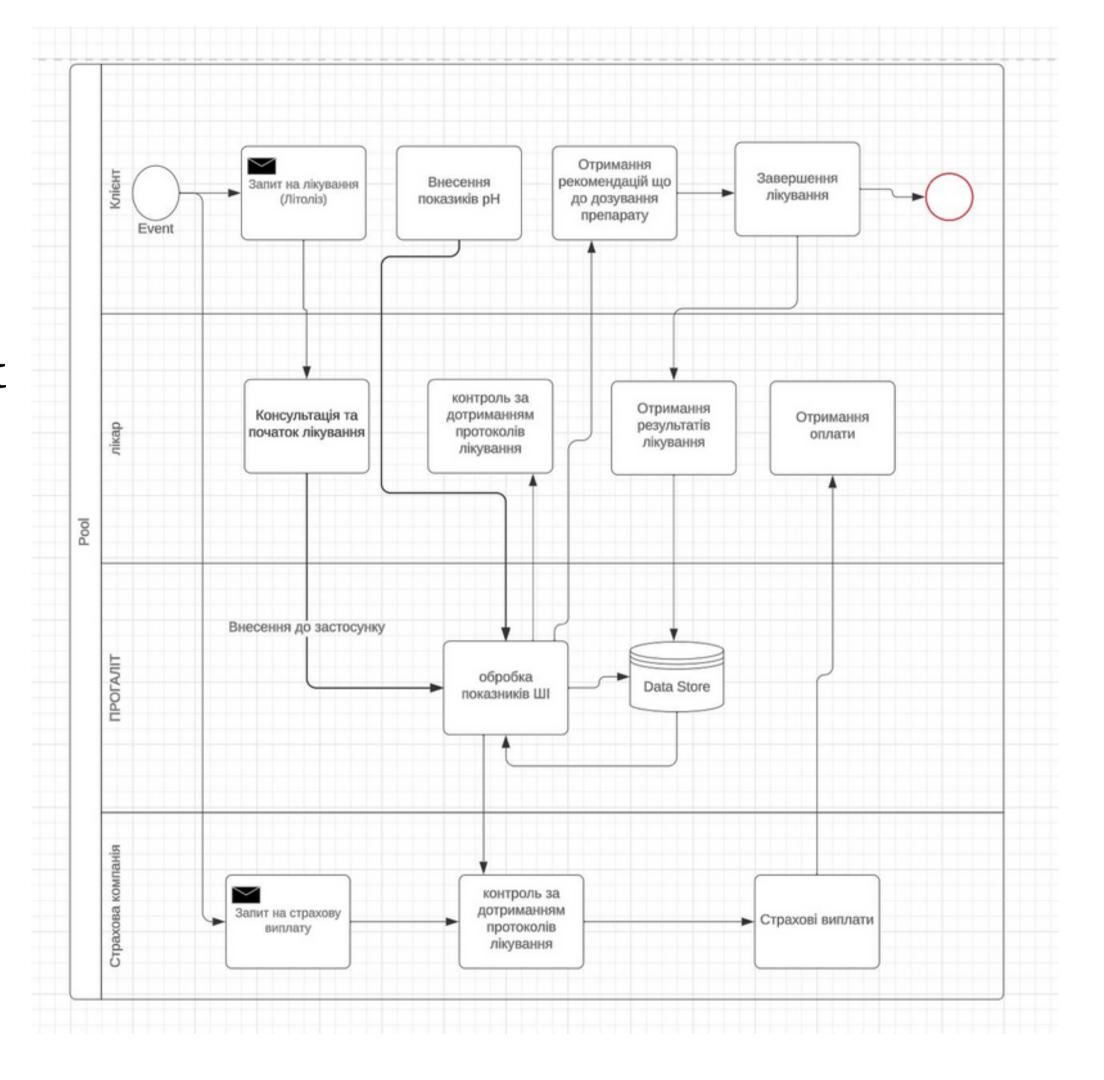
Disadvantages of Litholysis

- a large number of routine tasks for the patient and the doctor
- lack of possibility of treatment monitoring
- the risk of actual self-treatment of the patient without consulting a doctor



Advantages of Programmatic litholysis

- Automation of the treatment process;
- Remote monitoring of patient treatment and the possibility of correction of treatment in real time;
- Analysis of treatment effectiveness and prognosis of relapse based on artificial intelligence algorithms.



Advantages of using Progalit SaMD for clinics

- Improving the quality of litholysis for patients
- 2 A new type of service
- Cost reduction hour/patient
- Reducing the burden on doctors

Benefits of using Progalit SaMD for patients

- Reducing the duration of treatment and costs
- Improving the prognosis, reducing the likelihood of relapse
- Individual approach to treatment (recommendations on diet and drinking regime)
- Improved perception of treatment

Benefits of using Progalit SaMD for an insurance company

Automation of treatment and monitoring allows insurance companies to confirm that treatment is taking place according to established protocols in real time.

Reduction of costs for reimbursement of insurance cases as a result of preventive measures

Advantages of using Progalit SaMD for a pharmaceutical company, a manufacturer of citrate mixtures

- Increase in sales
- Improving interaction with doctors and patients
- Obtaining new data on the effectiveness and safety of the drug

Thank Vou, ready for your questions!

