



Improving immune system  
to prevent cold sores.

Projected 100x Investment  
Return

Corporate Overview  
June 2023

# Safe Harbor Disclaimer



This presentation contains forward-looking statements. All statements other than statements of historical facts contained in this presentation, including statements regarding our future results of operations and financial position, business strategy, prospective products and product candidates and their development, regulatory approvals, ability to commercialize our products and product candidates and attract collaborators, reimbursement for our product candidates, research and development costs, timing and likelihood of success, plans and objectives of management for future operations, our ability to obtain and maintain intellectual property protection for our product candidates and their development, competing therapies, and future results of current and anticipated products and product candidates, are forward-looking statements. These statements involve known and unknown risks and uncertainties, such as experienced with the COVID-19 outbreak, and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, many of which are disclosed in detail in our reports and other documents filed with the Securities and Exchange Commission.

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# Highlights:

- Drug that **PREVENTS** cold sores
  - 50 million patients per year
  - The drug works. Effective in 3 of 3 clinical trials through Phase 2, no serious adverse events. It just trains the immune system.
  - Convenient dosing—topically **to the arm** for 2-6 hours, once every 3 months, during or between outbreaks
  - Nothing else approved for the indication or even in clinical trials
  - Late clinical stage. Completed a Phase 2 and End-of-Phase-2 Meeting with FDA
- 
- **Pre-IPO offering to accredited investors at \$3.00 per share for a limited time**
  - **Reasonable projection of 100x return in four years.**

# Maybe the Only Opportunity in Pharma With:



## 1. Statistically Significant Efficacy in 3 of 3 clinical trials

- Phase 1, Phase 2, and Mechanism of Action clinical trials completed, all with significant efficacy. Thus, there is low risk of failure in Phase 3.

## 2. Enormous Market

- 7 million persons in the U.S. alone have six or more outbreaks per year.
- 50 million people in U.S. have at least one outbreak in any given year.
- \$1.5 billion market for Treating herpes. Prevention of oral herpes not currently addressed

## 3. First in Class and Nothing Else Approved for the Indication

- No other drug approved for the prevention of cold sores
- No other drug even in clinical trials in U.S.
- Patent exclusivity to at least 2036.

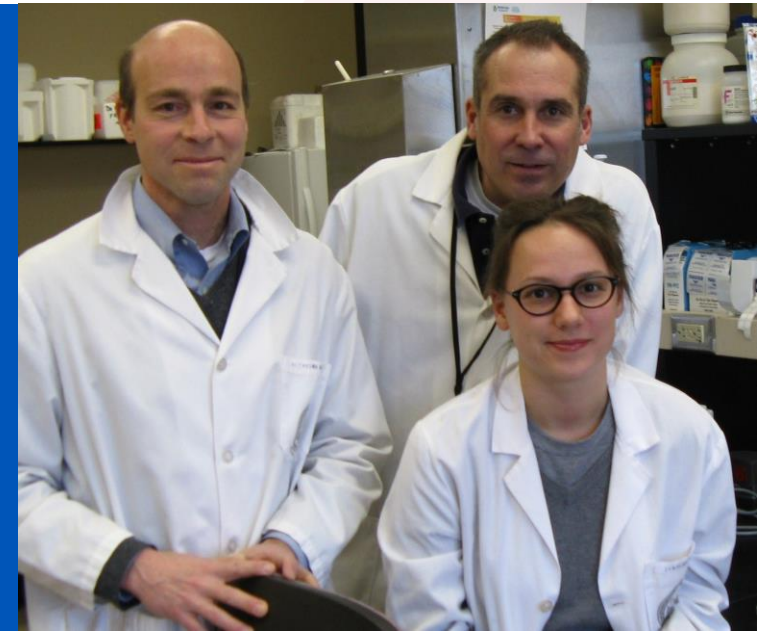
# Our origin story



**Dr Hugh McTavish** founded SquareX based on his own invention to treat his own cold sores. As a PhD biochemist and patent attorney, he was uniquely suited.

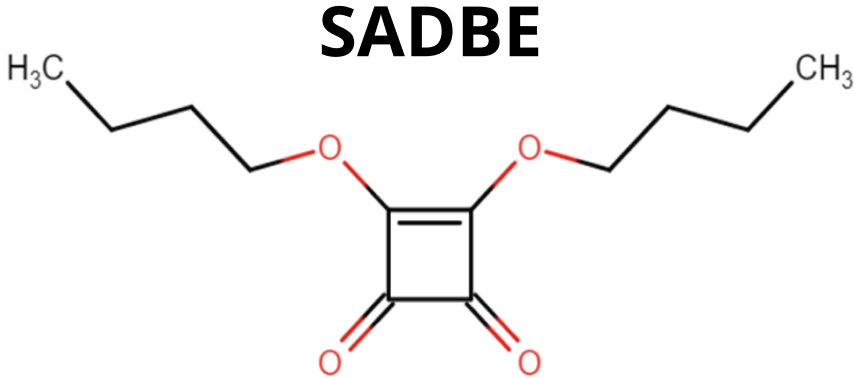
Hugh says, "The drug worked for me. I went from nearly constant cold sores to now I have not had one in years."

Dr McTavish also founded IGF Oncology with targeted cancer drugs he invented. IGF has had a successful exit by licensing its technology.



# Solution: SQX770

- **Active Ingredient: Squaric Acid Dibutyl Ester (SADBE)**
- **PREVENTS cold sore outbreaks**
- **Topical application, to the arm, not the cold sore**
- **Convenient dosing:**
  - Any time during or between outbreaks
  - One dose lasts 3 months
- **Statistically significant measures of efficacy in 3 of 3 clinical trials:**
  - Phase 1:** → 3x longer time to next outbreak vs. placebo
  - Phase 2:** → 2.6x fewer outbreaks in days 43-121 vs. placebo
  - Phase 2 mechanism of action:** → Significantly increased interferon-gamma and other measures of cellular immune response



# Clinical Trials – Phase 1

## Phase 1



- Conducted at Massachusetts General Hospital
- 43 adult subjects
  - 6 or more cold sore outbreaks annually
- Randomization schedule
  - Study medication
  - Placebo (DMSO)
- **Result: 3x longer time to next outbreak (highly significant,  $p < 0.01$ )**

# Clinical Trials – Phase 2

## Phase 2

- Conducted at Mass General and Stanford University
- 139 adult subjects
  - Reporting 4 or more cold sore outbreaks annually
- Randomization schedule
  - Active (SADBE)
  - Placebo (DMSO)
- **Results**
  - **2.6x fewer outbreaks ( $p < 0.05$ )**
  - **Outbreaks that happened were significantly less severe (0.3 vs. 1.3 in placebo on scale of 0-3)**





# Clinical Trials – Mechanism of Action Trial – SQX770 Improves Immune Response to HSV



By Every Measure, SQX770 Caused the Immune Response of Patients with 6+ Outbreaks to Become Better – More Like the Response of Healthy Persons with 0-2 Outbreaks

	Patients with 0-2 outbreaks (healthy)	Persons with 6+ outbreaks	Patients with 6+ outbreaks after SQX770
	Day 1	Day 1	Day 57 After Treatment On Day 1
T-cell proliferation to HSV-1	20.6	10.6	21.9
Anti-HSV-1 antibodies	6.9*	8.3	7.6
Interferon-gamma expression	3.28*	1	11.01**
Interleukin-5 expression	0.56*	1	0.56*
5 other immune genes	Higher*	1	Higher*
2 other immune genes	Lower*	1	Lower*

\* P<0.05, statistically significant  
\*\* P<0.01, highly significant

# Peer reviewed in the top journals



Chang ALS, Honari G, Guan L, Zhao L, Palli MA, Horn TD, Dudek AZ, McTavish H.

A phase 2, multi-center, placebo-controlled study of single dose squaric acid dibutyl ester (SADBE) to reduce frequency of outbreaks in subjects with recurrent herpes labialis.

***Journal of the American Academy of Dermatology*** 2020 Dec;83(6):1807-1809.



McTavish H, Zerebiec KW, Zeller JC, Shekels LL, Matson MA, Kren BT.

Immune characteristics correlating with HSV-1 immune control and effect of squaric acid dibutyl ester on immune characteristics of subjects with frequent herpes labialis episodes.

***Immunity, Inflammation and Disease***  
2019;7(1):22-40.



McTavish H, Kimball A, Horn TD. Immunotherapy of recurrent herpes labialis with squaric acid.

***JAMA Dermatology***  
2017;153:828-829.

# Competition. SQX770 is better than Valtrex



	VALTREX (Valacyclovir)	SQX770 (squaric acid dibutyl ester)
<b>Indication</b>	Treatment: reducing the duration of a single treated herpes labialis episode.	Prevention: Reducing the frequency and/or severity of future herpes labialis episodes.
<b>Dosing</b>	2 grams, one day. Must be given as early as possible in an episode, preferably on the first day, at the first sign of tingling or symptoms of a herpes labialis episode.	Topical to the arm (not to the lip or a lesion) once every 3 months. Can be given any time -- during or between herpes labialis episodes.
<b>Duration of episodes</b>	Reduces by 2 days (from about 10 days to about 8 days).	Not studied yet.
<b>Frequency of episodes</b>	<b>No effect.</b>	<b>2.6x reduction in frequency versus placebo.</b>
<b>Severity of episodes.</b>	<b>No effect.</b> Prescribing information says: "No significant difference was observed between subjects receiving VALTREX or placebo in the prevention of progression of cold sore lesions beyond the papular stage."	<b>Significant reduction in severity, from 1.4 in placebo group to 0.3 in treatment group on a 0-3 scale.</b>

# Other Disease Indications

Evidence suggests SquareX will be effective against these diseases:

- Genital herpes (patented)
- Yeast infection and fungal infections generally (patent pending)
- Molluscum contagiosum (common viral skin infection, patent pending)
- Common warts (not patented, but we will capture this market)

# Reasonable Projection of 100x Return on Investment

- \$3.00 per share = **\$22 Million** valuation of company
- Net Present Value calculated as **\$119 Million** now even with these conservative assumptions:
  - **Sales only to people with 6+ outbreaks**
  - and only half of them
  - Only 2 doses per year instead of the recommended 4
  - **No sales outside U.S.**
  - 30% discount rate
  - 4 years to get FDA approval instead of 3
  - No other indications besides cold sores
  - Only 59.4% chance of FDA approval (the historical average for Phase 3 drugs)
- Valuation after FDA approval, about **\$5,500 Million (= 250x current stock price)**
- Valuation with P/E of 10 at peak market penetration = **\$14,700 Million (=670x current stock price)**

# Valuation Model Projections:



## SquareX Pharmaceutical Corporation

		<u>Year-1</u>	<u>Year-2</u>	<u>Year-3</u>	<u>Year-4</u>	<u>Year-5</u>	<u>Year-6</u>	<u>Year-7</u>	<u>Year-8</u>	<u>Year-9</u>	<u>Year-10</u>	<u>Year-11</u>	<u>Year-12</u>	<u>Year-13</u>	<u>Year-14</u>	<u>Year-15</u>	<u>Year-16</u>	
						<u>FDA Approva l</u>												
Market Penetration						15%	30%	50%	80%	100%	100%	100%	100%	90%	80%	70%	60%	
	<u>Mkt (M)</u>	<u>Mkt Share (%)</u>																
Patients	7.0	50%	-	-	-	0.525	1.050	1.750	2.800	3.500	3.500	3.500	3.500	3.150	2.800	2.450	2.100	
Cost/dose			-	-	-	\$135	\$135	\$135	\$135	\$135	\$135	\$135	\$135	\$135	\$135	\$135	\$135	
Avg number of doses/year						2	2	2	2	2	2	2	2	2	2	2	2	
<b>Total Revenue (\$M)</b>			-	-	-	141.8	283.5	472.5	756.0	945.0	945.0	945.0	945.0	850.5	756.0	661.5	567.0	
Operations (incl CRO)			(6.4)	(12.6)	(23.0)	(23.0)	(3.0)	(3.1)	(3.2)	(3.3)	(3.4)	(3.5)	(3.6)	(3.7)	(3.8)	(3.9)	(4.0)	(4.2)
Cost of Goods Sold	15%		-	-	-	(21.3)	(42.5)	(70.9)	(113.4)	(141.8)	(141.8)	(141.8)	(141.8)	(127.6)	(113.4)	(99.2)	(85.1)	
BioVentures royalties (of net revenue)	5.5%		-	-	-	(6.6)	(13.3)	-	-	-	-	-	-	-	-	-	-	
Sales & Marketing (of net revenue)	20%		-	-	-	(24.1)	(48.2)	(80.3)	(128.5)	(160.7)	(160.7)	(160.7)	(160.7)	(144.6)	(128.5)	(112.5)	(96.4)	
Wholesalers (of net revenue)	15%		-	-	-	(18.1)	(36.1)	(60.2)	(96.4)	(120.5)	(120.5)	(120.5)	(120.5)	(108.4)	(96.4)	(84.3)	(72.3)	
<b>Total Expenses</b>			(6.4)	(12.6)	(23.0)	(23.0)	(73.1)	(143.2)	(214.6)	(341.6)	(426.3)	(426.4)	(426.5)	(426.6)	(384.4)	(342.2)	(300.1)	(257.9)
Adjusted EBITDA			(6.4)	(12.6)	(23.0)	(23.0)	68.7	140.3	257.9	414.4	518.7	518.6	518.5	518.4	466.1	413.8	361.4	309.1
	<u>Tax Rate</u>	<u>NOL</u>																
Income Taxes (IRS & State)	29%	0.2	-	-	-	-	(1.3)	(40.7)	(74.8)	(120.2)	(150.4)	(150.4)	(150.4)	(150.3)	(135.2)	(120.0)	(104.8)	(89.6)
<b>After Tax Cash Flow</b>			(6.4)	(12.6)	(23.0)	(23.0)	67.4	99.6	183.1	294.2	368.3	368.2	368.2	368.1	330.9	293.8	256.6	219.5
<b>Probability based on FDA Approval</b>	59.4%		100.0%	100.0%	100.0%	100.0%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%	59.4%
<b>Probability Adjusted AT Cash Flow</b>			(6.4)	(12.6)	(23.0)	(23.0)	38.8	59.2	108.8	174.8	218.8	218.7	218.7	218.6	196.6	174.5	152.4	130.4
	<u>Discount NPV (\$M)</u>																	
NPV After Tax Cash Flow	30.0%	225																
NPV Probability Adj AT Cash Flow	30.0%	119																
NPV in year 4 upon FDA approval	15.0%	1,380																
NPV upon FDA approval with more realistic assumptions	15.0%	5,520																
Valuation at P/E of 10 at peak revenue		14,700																

# Our Team



## Dr Hugh McTavish

*President, CEO, and Founder*

- Ph.D. biochemist and patent attorney
- Author of 18 scientific journal articles and inventor of 21 issued U.S. patents,
- Founded and successfully licensed prior biotech company



## Constantine Kardaras

*Chief Financial Officer*

- Over 30 years in Corporate Finance and Public Accounting, including six years at Deloitte
- Former Executive Director and CAO at Imunon, Inc., a publicly traded clinical stage biotech company
- C.P.A. and M.B.A. in Finance from NYU



## Thomas Horn M.D

*Founder and Advisor*

- Board certified dermatologist and dermatopathology Faculty at Harvard Medical School
- Former Executive Director of the American Board of Dermatology
- Co-inventor of the company's technology



## Kathleen Littrell

*VP Clinical Development*

- 20 years experience managing all phases of clinical trials

# Raised \$6M to date

## And successfully achieved:



- U.S. and foreign patents issued in key markets
- Preclinical testing and toxicology
- Phase 1 clinical trial
- Phase 2 mechanism of action clinical trial
- Phase 2 clinical trial
- End of phase 2 meeting with the FDA
- Audit of financials for initial public offering



# Corporate and Clinical Goals

- Complete IPO
  - ✓ S-1 filed with SEC in January 2023
    - List on NASDAQ
- Conduct 6-month Phase 2 Bridging clinical trial\*
- Conduct two simultaneous 12-month Phase 3 clinical trials\*
- File New Drug Application (NDA)

\* Timing dependent on receipt of funding



# Key Takeaways

**Realistic possibility of 100x return on investment.**

**No other opportunity in pharmaceuticals exists with:**


- **Drug shown effective through Phase 2 trials**
- **Enormous indication with 7 million people in U.S. with 6+ outbreaks per year, and 50 million with 1+ outbreaks in U.S. alone**
- **No other drug approved for the indication or even in clinical trials**




# THANK YOU

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