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Peter Thiel Associate Jim O'Neill, RFK Jr.'s Right-Hand Man At HHS And New CDC Acting Director, Took Money From, Helped Incubate, Or Was Otherwise Linked To At Least Eight Medical Industry Startups With Direct Business Before The Department He Could Help Run

SUMMARY: Deputy HHS Secretary **Jim O'Neill**, a close associate of venture capitalist Peter Thiel, has just been named acting director of the Centers for Disease Control and Prevention (CDC) "after a clash over vaccine policy ended in the departure of several agency leaders." O'Neill was a managing director at **Mithril Capital**, Thiel's venture capital firm, and the former CEO of the **Thiel Foundation**, has ties to numerous health and medical companies with business interests before the Department of Health and Human Services.

Several are named on his financial disclosure (OGE form 278e) and LinkedIn profile:

- From 2023-2025, O'Neill was a director and advisor at **ADvantage Therapeutics**, a pharmaceutical company preparing for clinical trials in the U.S. from which he received six-figure compensation in 2024-2025. O'Neill was also a director of Klothea Bio, a development-stage subsidiary of ADvantage.

- From 2022-2025, O'Neill was a paid "global health advisor" for **Rational Vaccines**, a herpes vaccine research and development company that has sought and received NIH grant funding and launched multiple clinical trials.

- From 2024-2025, O'Neill was a paid advisor for **Arcadia Medicine**, a mental health therapeutics startup with a drug in the preclinical stage as of April 2025.

- From 2019-2021, O'Neill was a board observer of **Oisín Biotechnologies**, a company in preclinical stages for a gene therapy treatment as of September 2024.

O'Neill also co-founded Breakout Labs, a science seed funding nonprofit that was spun out into Breakout Ventures, a venture capital firm with several medical industry startups in its portfolio, including:

- **Cytovale**, a medical device startup that, as of April 2025, had received grant funding from the NIH and BARDA and had products dependent on FDA approval.

- **Immusoft**, a medical startup that was awarded millions in NIH funding between 2012-2020 and was undergoing clinical trials in the U.S. as of 2024.

- **ShiraTronics**, a clinical-stage migraine therapy company that builds medical devices dependent on FDA approval.

- **STRM.BIO**, a gene therapy startup that was awarded millions in NIH funding in 2022-2023.

On his ethics agreement, O'Neill promised to divest from ADvantage Therapeutics and abstain from participating in matters directly involving ADvantage, Klothea Bio, Rational Vaccines, and Arcadia Medicine. However, he did not promise to abstain from decisions involving these companies for the duration of his term, or to abstain from doing business with them after departing HHS.

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In a 2014 speech, O'Neill advocated for radically altering the FDA's drug approval rules to allow Americans to use drugs allegedly proven "safe" to use drugs "at their own risk" before they have been proven effective. Health experts have expressed alarm at O'Neill's statements, which they argued demonstrate a

lack of knowledge about how the FDA's review process, noting that "every drug has risks" the FDA must weigh against the potential benefits of effective treatment.

HHS Deputy Secretary, Jim O'Neill, Is A "Close Associate" Of Billionaire Peter Thiel Who Previously Held Leadership Positions At Mithril Capital, Thiel's Venture Firm, And The Thiel Foundation

Jim O'Neill Is The Pending Nominee To Be HHS Deputy Secretary, Potentially Serving As HHS Secretary Robert F. Kennedy Jr.'s "Right-Hand Man"

November 2024: Then-President-Elect Trump Picked Jim O'Neill To Be Deputy Secretary At The U.S. Department Of Health And Human Services (HHS), Where He Would Serve As "Right-Hand Man" To Secretary Robert F. Kennedy Jr. "President-elect Donald Trump tapped Jim O'Neill, a close associate of early Trump backer Peter Thiel, for HHS deputy secretary. 'He will oversee all operations and improve Management, Transparency, and Accountability to, Make America Healthy Again,' Trump said in a statement, nodding to the operational role O'Neill will play as a right-hand man to HHS Secretary pick Robert F. Kennedy Jr." [Politico, 11/26/24]

- **Headline: Trump Picks Jim O'Neill For No. 2 Spot At HHS.** "Trump picks Jim O'Neill for No. 2 spot at HHS." [Politico, 11/26/24]

- **February 2025: Robert F. Kennedy Jr. Was Confirmed As HHS Secretary.** "Despite millions of dollars spent by groups opposed to his nomination, the Senate voted to install Robert F. Kennedy Jr. at the helm of the Department of Health and Human Services." [NPR, 2/13/25]

O'Neill Was Confirmed In June 2025. "O'Neill, confirmed by the Senate in June, will continue as HHS deputy while temporarily leading the CDC." [Fox 5 Atlanta, 08/28/25]

O'Neill Has Pushed To Alter FDA Rules To Allow Experimental Drug Use By Consumers "At Their Own Risk" After Drugs Have Been Proven Safe, But Not Effective—A Stance That Alarmed Experts, Who Have Noted That "'Every Drug Has Risks'" The FDA Weighs Against The Benefits Of Effective Treatment

In A 2014 Speech, O'Neill Said That He Supported Altering FDA Approval Rules Around Drug Approval To "'Let People Start Using Them, At Their Own Risk'" After They've Been Proven Safe, But Without Proof Of Efficacy. "O'Neill also could push the agency in new directions. In a 2014 speech, he said he supported reforming FDA approval rules so that drugs could hit the market after they've been proven safe, but without any proof that they worked, something he called 'progressive approval.' 'We should reform FDA so there is approving drugs after their sponsors have demonstrated safety -- and let people start using them, at their own risk, but not much risk of safety,' O'Neill said in a speech at an August 2014 conference called Rejuvenation Biotechnology. 'Let's prove efficacy after they've been legalized.'" [Bloomberg, 12/7/16]

- **O'Neill: "Let's Prove Efficacy After They've Been Legalized."** "'We should reform FDA so that it's approving drugs after their sponsors have demonstrated safety and let people start using them at their own risk, but not much risk of safety,' O'Neill said. 'But let's prove efficacy after they've been legalized.'" [The Hill, 12/8/16]

Experts Reportedly Expressed Alarm At O'Neill's Comments, Stating That It Is All But Impossible To Separate The Questions Of Safety And Efficacy, Given That "'Every Drug Has Risks'" And The FDA Must Balance Risks Against How Effective The Drug Could Be. "Experts expressed alarm at those remarks, saying that they demonstrated a lack of knowledge of how the FDA's review process works, and that it is all but impossible to separate the questions of safety and efficacy. 'People need to understand that safety doesn't exist without the balance of risk,' said Peter Pitts, president of the Center for Medicine in the Public Interest and a former FDA associate commissioner under President George W. Bush. He said that 'every drug has risks,' so the important consideration is balancing the risks against how effective the drug will be. Side effects that would never be approved for Aspirin might be approved for a lung cancer drug, he noted." [The Hill, 12/8/16]

O'Neill Oversees The Daily Operations Of The FDA And Play An Important Role In Overseeing The Development Of Federal Health Regulations

If Confirmed, O'Neill "Will Oversee The Daily Operations Of HHS' Subagencies, Including The FDA And CMS," And Will Play An Integral Role In Overseeing The Development Of Federal Health Regulations. "If his nomination for deputy HHS secretary is approved, O'Neill will oversee the daily operations of HHS' subagencies, including the FDA and CMS, and will play an integral role in public health emergency preparedness and overseeing the development of federal health regulations." [Association for Diagnostics and Laboratory Medicine, 3/1/25]

O'Neill Is A "Close Associate" Of Billionaire "'Kingmaker'" Peter Thiel, Formerly Serving As Managing Director Of Thiel's Venture Firm Mithril Capital And As A Former CEO Of The Thiel Foundation

O'Neill Is A "Close Associate" Of Billionaire Peter Thiel, A "Longtime" Elon Musk Associate Known As A "'Kingmaker' In Trumpland." "President-elect Donald Trump tapped Jim O'Neill, a close associate of early Trump backer Peter Thiel, for HHS deputy secretary." [Politico, 11/26/24]

- **Billionaire Peter Thiel, Formerly The CEO Of PayPal And "A Longtime [Elon] Musk Associate," "Helped Bankroll" Vice President J.D. Vance's 2022 Senate Campaign.** "One, a senior adviser to the director, is a 21-year-old whose online résumé touts his work for Palantir, the government contractor and analytics firm cofounded by billionaire Peter Thiel, who is its chair. (The former CEO of PayPal and a longtime Musk associate, Thiel is a Trump supporter who helped bankroll the 2022 Senate campaign of his protégé, Vice President JD Vance.)." [Wired, 1/28/25]

- **Thiel Was Called A "'Kingmaker' In Trumpland" After Trump Named His "Protégé" J.D. Vance As His Vice Presidential Running Mate.** "The Palantir chairman has been described as a 'kingmaker' in Trumpland after Trump picked Thiel protégé JD Vance as his running mate." [Axios, 1/3/22]

O'Neill Was The Former CEO Of The Thiel Foundation And Co-Founded The Thiel Fellowship. "The rise of the former CEO of the Thiel Foundation comes years after O'Neill was in the mix to be Trump's first FDA commissioner in his first term." [Politico, 11/26/24]

- **The Thiel Foundation Provides $100,000 Fellowships To Individuals It Claims Are "Set To Disrupt Various Industries."** "The Thiel Foundation has unveiled the 2024 class of Thiel Fellows, assembling a group of 20 brilliant young minds who are set to disrupt various industries. Established in 2011, the Thiel Fellowship provides each recipient with $100,000 and access to a powerful network of tech founders, investors, scientists, and former fellows." [Thiel Foundation via BusinessWire, 5/21/24]

2012-2019: O'Neill Was A Managing Director At Peter Thiel's Venture Fund Mithril Capital, Which Employed J.D. Vance During O'Neill's Tenure. "O'Neill worked as a managing director at Thiel's Mithril Capital and sits on the board of directors of ADvantage Therapeutics, a pharmaceutical company developing treatments for neurodegenerative conditions, according to his LinkedIn." [Politico, 11/25/24]

- **O'Neill Was Managing Director At Mithril Capital Management From March 2012 To March 2019:**

[Jim O'Neill via Linkedin, accessed 4/16/25]

- **Vice President J.D. Vance Worked At Mithril, A Venture Fund, From 2016 To 2017.** "J.D. Vance's bona fides for a run to the U.S. Senate in 2022 largely rested on two things—the success of his Rust Belt memoir, Hillbilly Elegy, which captured the plight of the white working class, and a career in venture capital that began in 2016 at Mithril, the firm founded by billionaire investor and PayPal cofounder Peter Thiel. [...] Vance left Mithril in the spring of 2017 to join Revolution, the investment firm started by AOL cofounder Steve Case." [Fortune, 7/26/24]

After Seven Years, In March 2019, Jim O'Neill Left Mithril Capital Shortly After "Unanswered Questions" About The Firm's Finances Emerged In February 2019, Prompting A Federal Probe By September 2019—O'Neill Later Sued Mithril Co-Founder Ajay Royan Alleging His 2019 Termination Was Due To Royan's "Erratic Behavior"

September 2019: Federal Investigators, Including The FBI, Were Probing Mithril Capital Over "Concerns Of Possible Financial Misconduct." "Federal investigators are probing the conduct and practices of Mithril Capital, a venture capital firm co-founded by Peter Thiel, Recode has learned. US officials — including the FBI — have in recent months questioned some people close to Mithril regarding concerns of possible financial misconduct at the firm, according to people familiar with the matter who insisted on anonymity given its sensitivity. Mithril confirmed in a statement that its lawyers are in touch with government authorities." [Vox, 9/12/19]

Jim O'Neill Left Mithril Capital In March 2019, Shortly After Reporting On "Unanswered Questions" In The Firm's Finances Emerged In February 2019. "In the months since Recode reported on unanswered financial questions at Mithril, things have deteriorated, according to people familiar with the matter. The firm has lost staff and has adopted a more defensive posture. Two of the other managing directors at Mithril, Crystal McKellar and Jim O'Neill, recently left the venture capital firm in contentious exits, the people say — departures that until now haven't previously been reported." [Vox, 9/12/19]

- **O'Neill Left Mithril Capital Management In March 2019.** [Linkedin, accessed 4/16/25]

- **Reporting About "Unanswered Questions" In Mithril's Finances Emerged In February 2019.** "Seven years ago, a smooth-talking associate of Peter Thiel promised that he had launched the "capstone" to Thiel's investment empire, naming their new firm after a mythical metal in Lord of the Rings because it was flashy yet permanent. [...] But Mithril Capital is primarily associated with some other things these days: drama, disarray, and unanswered questions about its finances." [Vox, 2/18/19]

May 2023: Jim O'Neill Sued Former Mithril Managing Director And Co-Founder Ajay Royan, With O'Neill Blaming His 2019 Termination From Mithril On Royan's "'Erratic Behavior.'" "A former director at Peter Thiel's venture capital firm Mithril Capital claims in a lawsuit he was driven out of his job by 'dysfunctional and toxic' management. The complaint by James 'Jim' O'Neill, filed in San Francisco Superior Court, is the latest fallout over alleged mismanagement at the firm that spilled into public view about four years ago when its former general counsel filed a lawsuit. [...] He blames his 2019 termination at Mithril on 'erratic behavior' by

managing director Ajay Royan, who co-founded Mithril in 2012 after a previous stint at Thiel's defunct hedge fund Clarium Capital, where O'Neill also worked." [Bloomberg, 5/20/23]

O'Neill Has Been Affiliated With Numerous Medical Companies Throughout His Career, Raising Questions Of Conflicts Of Interest Should He Be Confirmed

O'Neill's Career Chronology, Depicted Below, Indicates That He Has Held Numerous Roles With Health Companies Over The Last Two Decades:

Date(s)	Role	Employer
March 2023-Present	Board of Directors	ADvantage Therapeutics Inc.
August 2020-Present	Advisor	FounderPool
October 2019-November 2021	CEO October 2019-July 2021 Board of Directors April 2010-November 2021	SENS Research Foundation
October 2019-July 2021	Board Observer	Oisin Biotechnologies
March 2012-March 2019	Managing Director	Mithril Capital Management LLC
December 2011-December 2015	Investment Committee	Breakout Labs
October 2010-June 2014	Co-Founder	Thiel Fellowship
May 2009-June 2012	CEO (Acting)	The Thiel Foundation
October 2008-June 2012	Managing Director	Clarium Capital Management
June 2008-October 2008	Member	Suitability and Security Clearance Performance Accountability Council
December 2002-October 2008	Principal Associate Deputy Secretary November 2007-October 2008 Steering Committee, BARDA June 2006-October 2008 Associate Deputy Secretary August 2005-November 2007 Director, Speech and Editorial Division December 2002-August 2005	U.S. Department of Health and Human Services
March 2001-December 2002	Senior Speechwriter	U.S. Department of Education

[Jim O'Neill via Linkedin, accessed 4/15/25]

O'Neill Has "Advised, Invested In, And Nurtured More Than Seventy Science And Technology Companies," According To His Biography For The Foresight Institute, Where He Was Listed As A "Mentor," As Of April 2025. "Jim has advised, invested in, and nurtured more than seventy science and technology companies." [Foresight Institute, accessed 04/02/25]

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[Foresight Institute, accessed 4/2/25]

- **The Foresight Institute Claims To Advance "Frontier Biotech, Neurotech, Nanotech, And AI For The Benefit Of Life."** "Foresight Institute is a non-profit advancing frontier biotech, neurotech, nanotech, and AI for the benefit of life." [Foresight Institute, accessed 4/2/25]

Prior To His Nomination, O'Neill Was A Director, Paid Advisor, Or Board Observer Of Several Companies With Business Interests Impacted By HHS

From 2023-2025, O'Neill Was A Director And Advisor At ADvantage Therapeutics, A Pharmaceutical Company Preparing For Clinical Trials In The U.S. From Which He Received Six-Figure Compensation In 2024-2025

Jim O'Neill Was A Director And Paid Advisor At ADvantage Therapeutics From 2023-2025.

#	ORGANIZATION NAME	CITY, STATE	ORGANIZATION TYPE	POSITION HELD	FROM	TO
		[…]				
4	ADvantage Therapeutics, Inc.	Miami, Florida	Corporation	Member, Board of Directors	3/2023	Present
5	ADvantage Therapeutics, Inc.	Miami, Florida	Corporation	Advisor	1/2023	Present

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

O'Neill Disclosed Six-Figure Compensation From Advantage Therapeutics In 2024-2025.

#	DESCRIPTION		EIF	VALUE	INCOME TYPE	INCOME AMOUNT
		[…]				
4	ADvantage Therapeutics, Inc.		N/A		Advisor Fees	$55,000
5	ADvantage Therapeutics, Inc., advisor fees: cash receivable	See Endnote	N/A	$15,001 - $50,000		None (or less than $201)
6	ADvantage Therapeutics, Inc., anticipated bonus		N/A	$50,001 - $100,000		None (or less than $201)
7	ADvantage Therapeutics, Inc., vested stock options		N/A	$1,001 - $15,000		None (or less than $201)
8	ADvantage Therapeutics, Inc., unvested stock options		N/A	$15,001 - $50,000		None (or less than $201)

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

- **O'Neill Promised To Forfeit All ADvantage Stock Options Unvested At The Time Of His Resignation From The Company's Board And Divest Vested Stock Options Within 90 Days Of Confirmation.** "I own vested and unvested stock options for shares of ADvantage stock. I do not own stock, vested or unvested restricted stock units, restricted stock, or any other equity interests in

ADvantage… I will forfeit all ADvantage stock options that are unvested at the time of my resignation. I will divest my vested stock options in ADvantage as soon as practicable but not later than 90 days after my confirmation." [OGE, Ethics Agreement of Jim O'Neill, 3/28/25]

ADvantage Therapeutics Is A Pharmaceutical Company That Develops Therapies To Treat Neurodegenerative Conditions, Including AD04, An Injectable Therapy To Treat Early Alzheimer's Disease. "Headquartered in the Wynwood neighborhood in Miami, ADvantage Therapeutics is developing therapies to treat neurodegenerative conditions with a central focus on Alzheimer's disease. The Company's lead compound AD04™ is an injectable therapy in the process of entering into a confirmatory Phase 2b clinical trials in Europe to evaluate safety and efficacy of the product in early Alzheimer's Disease." [LinkedIn, accessed 4/2/25]

- **As Of April 2025, ADvantage Therapeutics Stated It Was Preparing For Clinical Trials In The United States.** "ADvantage Therapeutics is developing therapies to treat neurodegenerative conditions with a major focus on Alzheimer's Disease (AD). We are currently preparing for clinical trials in Europe and in the US." [ADvantage Therapeutics, accessed 4/8/25]

- **The U.S. Food And Drug Administration, An HHS Agency, "Oversees Clinical Trials."** "Protecting the rights, safety and welfare of people who participate in clinical trials is a critical aspect of the FDA's mission. FDA oversees clinical trials to ensure they are designed, conducted, analyzed and reported according to federal law and good clinical practice (GCP) regulations." [U.S. Food and Drug Administration, accessed 4/8/25]

O'Neill Claimed He Would Resign From His Positions With ADvantage Therapeutics Upon Confirmation. "Upon confirmation, I will resign from my positions with ADvantage Therapeutics, Inc. ('ADvantage')." [U.S. Office of Government Ethics, accessed 4/8/25]

O'Neill Is A Director Of Klothea Bio, A Subsidiary Company Of ADvantage Therapeutics Launched In 2024 To Conduct R&D Around A Protein Relevant To Several Age-Associated Conditions

Klothea Bio Is A Subsidiary Company Of ADvantage Therapeutics Launched In 2024 To Conduct Research And Development Around Klotho, A Protein That Could Lead To Treatments And Prevention Of "Various Age-Associated Conditions." Advantage Therapeutics Inc., a leader in developing therapies targeting age-related diseases, announced today the formation of its new subsidiary, Klothea Bio, Inc., which will focus exclusively on the research and development of Klotho-based therapies to prevent and treat various age-associated conditions. The new subsidiary is backed by seed funding led by Longevitytech.fund ("LTF"), a prominent venture capital fund managed by Petr Sramek that invests in biotechnology startups focused on healthy lifespan extension globally." [ADvantage Therapeutics, 11/25/24]

Jim O'Neill Is A Member Of Klothea Bio's Board Of Directors.

#	ORGANIZATION NAME		CITY, STATE	ORGANIZATION TYPE	POSITION HELD	FROM	TO
	[…]						
6	Klothea Bio, Inc. (wholly owned subsidiary of ADvantage Therapeutics, Inc.)	See Endnote	Miami, Florida	Corporation	Member, Board of Directors	9/2024	10/2024

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

O'Neill Was A Paid "Global Health Advisor" For Rational Vaccines, A Herpes Vaccine Research And Development Company That Has Sought And Received NIH Grant Funding And Launched Multiple Clinical Trials

O'Neill Was A "Global Health Advisor" At Rational Vaccines From 2022-2025.

#	ORGANIZATION NAME	CITY, STATE	ORGANIZATION TYPE	POSITION HELD	FROM	TO
[…]						
7	Rational Vaccines, Inc.	Miami, Florida	Corporation	Global Health Advisor	1/2022	Present

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

O'Neill Received Between $15,001 And $50,000 In Consulting Fees From Rational Vaccines In 2024-2025.

#	DESCRIPTION	EIF	VALUE	INCOME TYPE	INCOME AMOUNT
[…]					
9	Rational Vaccines, Inc. (herpes vaccines development), consulting fees: cash receivable	See Endnote	N/A	$15,001 - $50,000	None (or less than $201)

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

Rational Vaccines Is An Infectious Disease Startup Working To Develop Treatments For Herpes. "We are an investigational-stage infectious disease company focused on combating all diseases resulting from herpes simplex virus 1 (HSV-1) and herpes simplex virus 2 (HSV-2) infections… Using our proprietary technology, we are developing rationally engineered, live attenuated viral immunotherapeutic and prophylactic vaccine candidates. Our aim is to help improve lives by reducing the suffering of those infected and reduce the spread of the virus. Our goal is to revolutionize the treatment, prevention, and diagnosis of herpes and herpes-related diseases worldwide. We envision a future where the world is free of herpes." [Rational Vaccines, accessed 4/16/25]

In 2023, The NIH Awarded Rational Vaccines Grants Worth $2.8 Million. "Rational Vaccines (RVx) was recently awarded $2.8 million in National Institute of Health (NIH) funding to help further its research to diagnose, treat and prevent the spread of the Herpes Simplex Virus (HSV)." [Rational Vaccines, 10/13/23]

December 2021: Rational Vaccines Announced A Clinical Trial. "Rational Vaccines, a company focused on revolutionizing the treatment and prevention of herpes to eradicate the disease, today announced the launch of a clinical trial designed to investigate the disease burden of herpes simplex virus types 1 and 2 (HSV-1 and HSV-2) in patients with HIV infection. The study, 'A 48 Week Observational Study of the Frequency of Symptomatic Herpes Virus I and II in HIV Infected Subjects,' will be led by Jorge E. Rodriguez, MD and conducted at the Global Research Institute in Los Angeles, CA." [Rational Vaccines, 12/14/21]

August 2022: Rational Vaccines Announced A Clinical Trial. "Rational Vaccines, a company focused on revolutionizing the treatment and prevention of herpes to eradicate the disease, today announced the launch of a clinical trial designed to determine the baseline characteristics of patients diagnosed with recurrent symptomatic herpes simplex virus type 2 (HSV-2). In addition to assessing the typical baseline characteristics of population, the purpose of this study is also to determine the acceptance of clinical trial procedures and understand the interest of the target patient population to participate in a therapeutic Phase 1/2 HSV-2 vaccine study." [Rational Vaccines, 8/15/22]

O'Neill Was A Paid Advisor For Arcadia Medicine, A Mental Health Therapeutics Startup With A Drug In The Preclinical Stage As Of April 2025

O'Neill Was An Advisor For Arcadia Medicine From 2024-2025.

#	ORGANIZATION NAME	CITY, STATE	ORGANIZATION TYPE	POSITION HELD	FROM	TO
[…]						
3	Arcadia Medicine, Inc.	San Francisco, California	Corporation	Advisor	4/2024	Present

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

O'Neill Received $4,500 In Consulting Fees And Between $1,001 And $15,000 In Cash Receivable From Arcadia Medicine In 2024-2025.

#	DESCRIPTION		EIF	VALUE	INCOME TYPE	INCOME AMOUNT
1	Arcadia Medicine, Inc. (mental health therapeutics)		N/A		Consulting Fees	$4,500
2	Arcadia Medicine, Inc., consulting fees: cash receivable	See Endnote	N/A	$1,001 - $15,000		None (or less than $201)

[Office of Government Ethics, OGE form 278e of James O'Neill, 3/31/25]

Arcadia Medicine Is A Mental Health Therapeutics Startup Working With MDMA And Psychedelics. "Arcadia Medicine is advancing a pipeline of promising therapeutic candidates designed to address mental health disorders that were previously intractable or inadequately addressed… Designed to be a non-racemic, non-neurotoxic form of MDMA with an improved therapeutic profile [...] Designed to be a short-acting psychoactive-empathogen combination therapy with an improved therapeutic profile [...] A subperceptual psychoactive drug designed to produce a short acting effect for use in a traditional hour-long therapeutic setting." [Arcadia Medicine, accessed 4/16/25]

As Of April 2025, Arcadia Medicine's Drugs Were In Either Preclinical Or Development Stages.

[Arcadia Medicine, accessed 4/16/25]

As Of April 2025, The FDA Has Designated Formulations Of Psilocybin And Of MDMA As "Breakthrough [Therapies]" To Treat Mental Health Disorders. "The FDA has also granted "breakthrough therapy" designation for two formulations of psilocybin being studied for safety and efficacy as a medical treatment for depression. The FDA also designated MDMA a breakthrough therapy to expedite research for it as a treatment for post-traumatic stress disorder." [NIH, accessed 4/16/25]

From 2019-2021, O'Neill Was A Board Observer Of Oisín Biotechnologies, A Biotechnology Company In Preclinical Stages For A Gene Therapy Treatment As Of 2024

O'Neill Was A Board Observer Of Oisín Biotechnologies From 2019-2021.

Board Observer
Oisin Biotechnologies · Part-time
Oct 2019 - Jul 2021 · 1 yr 10 mos

Senescent cells secrete molecules that cause inflammation in an effort to attract immune cells that would usually clear them. But as we age, for reasons that are not fully known, persistently senescent cells accumulate, leading to a vast number of age-related diseases. Oisín is developing a highly precise, patent-pending, DNA-targeted intervention to clear these cells. As a recent study has shown, clearing senescent cells both reduces negative effects of aging pathologies and also extends median lifespan and survival.

[Jim O'Neill via LinkedIn, accessed 4/16/25]

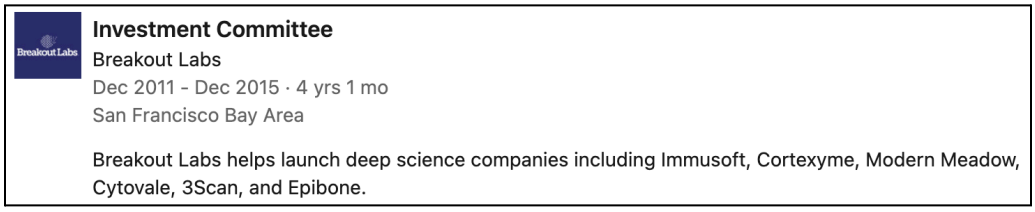
Oisín Biotechnologies Is A Biotechnology Company "Focused On Mitigating The Effects Of Age-Related Diseases" That, As Of 2024, Were In Preclinical Stages For A Gene Therapy Treatment. "Oisín Biotechnologies (Oisín), a privately held biotechnology company focused on mitigating the effects of age-related diseases, today announced the publication of preclinical data from its follistatin (FST) gene therapy program to mitigate muscle loss in an article titled 'Safe and Effective Delivery of DNA and RNA Using Proteolipid Vehicles' in Cell… The published data include results from studies conducted by Oisín scientists evaluating the impact of administering a single dose of FAST-PLV FST gene therapy in mice, over time." [Businesswire, 9/10/24]

O'Neill Was A Founder Of Breakout Labs, A Science Seed Funding Nonprofit From Which Breakout Ventures Spun Out; Breakout Ventures Is A Venture Capital Firm Invested In A Number Of Medical Companies That Have Contended For HHS Funding Or Have Products Whose Success Hinges On FDA Approval

O'Neill Co-Founded Breakout Labs, A Science Startup Seed Funding Group That Has Since Spun Out Into Breakout Ventures, A VC Firm With Numerous Medical Startups In Its Portfolio As Of April 2025

O'Neill "Helped Create Deep Science Fund Breakout Labs." "SENS Research Foundation - Jim has advised, invested in, and nurtured more than seventy science and technology companies. While running the Thiel Foundation, he co-founded the Thiel Fellowship and helped create deep science fund Breakout Labs." [Foresight Institute, accessed 4/16/25]

O'Neill Was On Breakout Labs' Investment Committee From 2011-2015.



[Jim O'Neill via LinkedIn, accessed 4/15/25]

2017: Leaders From Breakout Labs Launched Breakout Ventures, A Venture Capital Firm That Would Invest In The Same Kind Of Companies Albeit Now With A Profit Motive. "Lindy Fishburne has spent most of the last six years heading up Breakout Labs, a San Francisco-based program that's underwritten by renowned investor Peter Thiel and that in 2011 began offering nascent science-focused startups up to $350,000 in funding with no strings attached… Little wonder that Fishburne — who was formerly senior vice president of investments at the Thiel Foundation — decided it might make sense to enlist her Breakout Labs colleagues — including its scientific director, Hemai Parthasarathy and portfolio director Julia Moore — and create a more traditional venture fund that can support some of these companies as they, yes, break out." [Tech Crunch, 9/14/17]

2021: Breakout Labs "[Wound] Down" Operations After Nine Years. "Peter Thiel's 'audacious' early-stage science Breakout Labs fund is winding down [...] The effort funded 50 companies over nine years, with those companies going on to raise more than $1 billion." [San Francisco Business Times, 7/8/21]

Breakout Ventures Had Numerous Medical And Health Tech Startups In Its Portfolio As Of April 2025. [Breakout Ventures, accessed 4/16/25]

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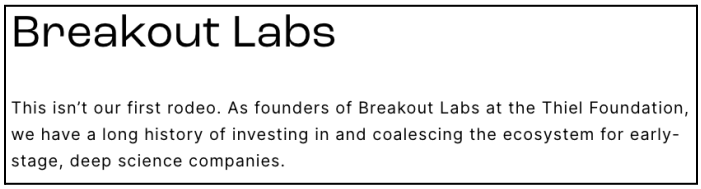
On Its Website, Breakout Ventures Named 41 Companies It Was Affiliated With Through Investments Made By "Breakout Labs At The Thiel Foundation"

Breakout Ventures' Website Named 41 Companies It Invested In "As Founders Of Breakout Labs At The Thiel Foundation."



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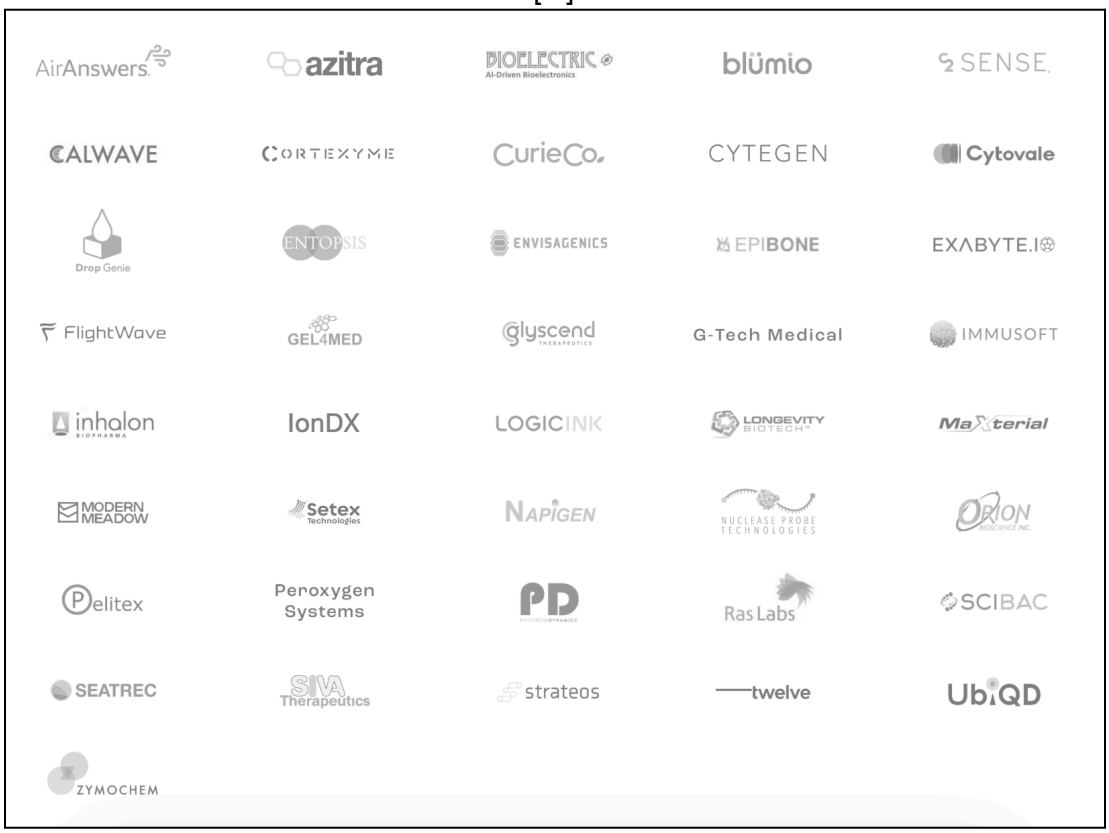
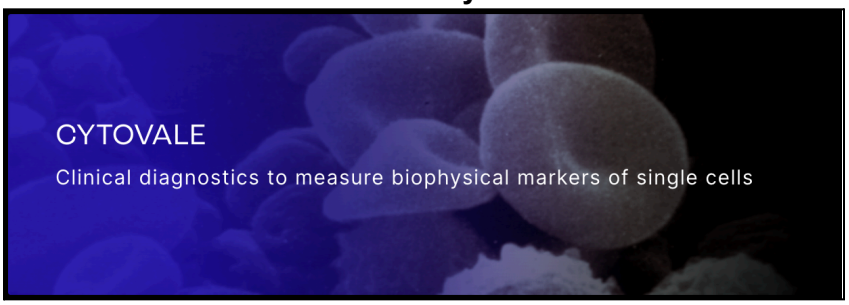


[Breakout Ventures, accessed 4/16/25]

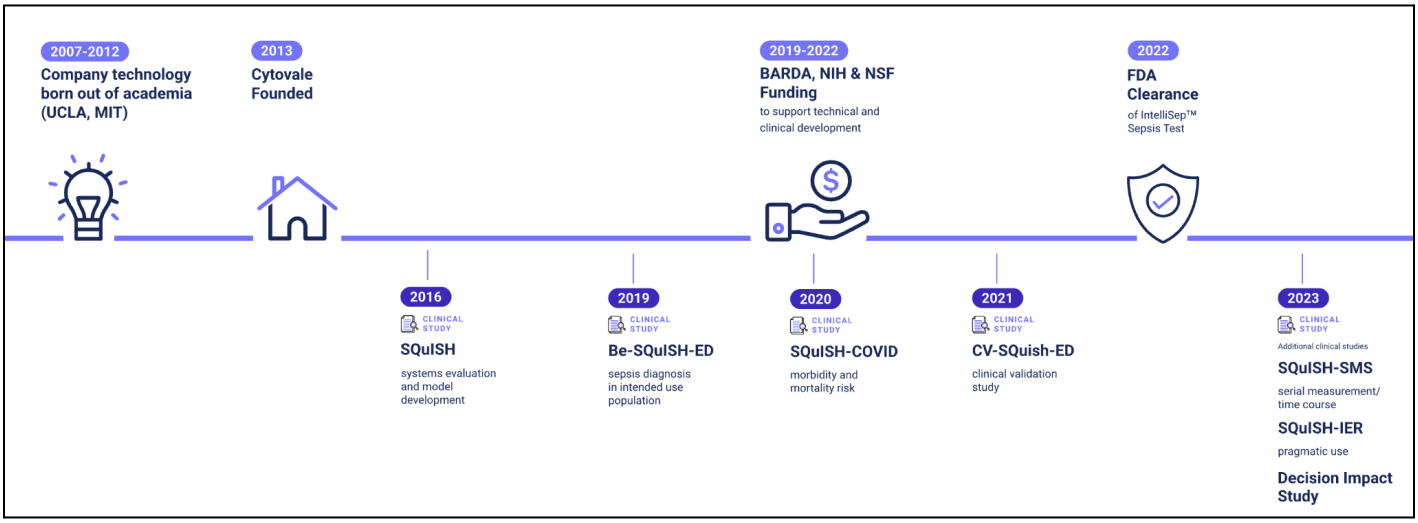
As Of April 2025, Breakout Ventures Was Invested In Cytovale, A Medical Device Startup That Has Received Millions In Funding From The NIH And BARDA And Has Products Dependent On FDA Approval

As Of April 2025, Breakout Ventures Was Invested In Cytovale.



[Breakout Ventures, accessed 4/16/25]

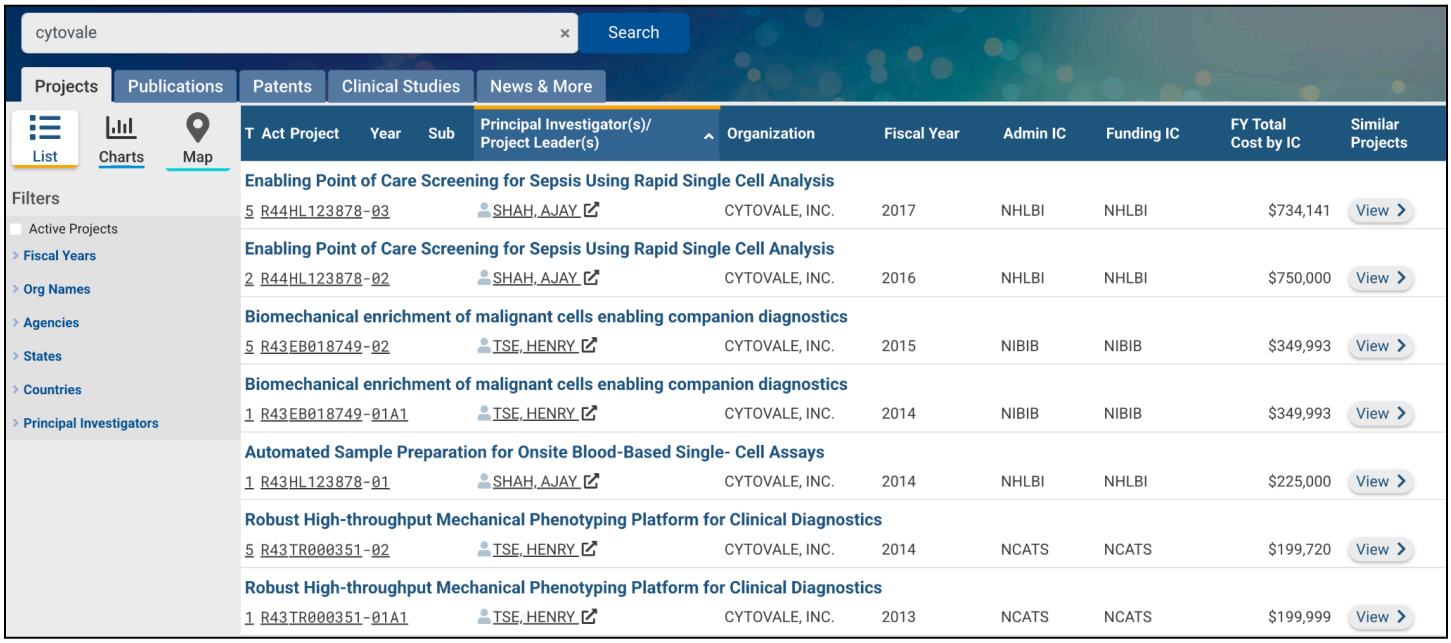
Cytovale Is A Medical Startup Founded In 2013.



[Cytovale, accessed 4/16/25]

Cytovale Built A Medical Device Used To Detect Sepsis That Has Received FDA Clearance. "The IntelliSep test detects sepsis by analyzing biophysical changes in white blood cells that occur early in the immune response to infection and signal risk for sepsis… IntelliSep is the first and only test FDA cleared for sepsis detection. Unlike traditional diagnostics that focus on identifying pathogens or measuring biomarkers, IntelliSep detects sepsis based on biophysical changes in immune cells that occur in response to systemic infection. IntelliSep gives providers a new way to understand sepsis and detect it earlier and more accurately than ever possible before." [Cytovale, accessed 4/16/25]

Cytovale Was Awarded Millions In Grant Funding From The NIH Between 2014-2017.



T	Act	Project	Year	Sub	Principal Investigator(s)/ Project Leader(s)	Organization	Fiscal Year	Admin IC	Funding IC	FY Total Cost by IC	Similar Projects
	5	Enabling Point of Care Screening for Sepsis Using Rapid Single Cell Analysis R44HL123878-03			SHAH, AJAY	CYTOVALE, INC.	2017	NHLBI	NHLBI	$734,141	View
	2	Enabling Point of Care Screening for Sepsis Using Rapid Single Cell Analysis R44HL123878-02			SHAH, AJAY	CYTOVALE, INC.	2016	NHLBI	NHLBI	$750,000	View
	5	Biomechanical enrichment of malignant cells enabling companion diagnostics R43EB018749-02			TSE, HENRY	CYTOVALE, INC.	2015	NIBIB	NIBIB	$349,993	View
	1	Biomechanical enrichment of malignant cells enabling companion diagnostics R43EB018749-01A1			TSE, HENRY	CYTOVALE, INC.	2014	NIBIB	NIBIB	$349,993	View
	1	Automated Sample Preparation for Onsite Blood-Based Single- Cell Assays R43HL123878-01			SHAH, AJAY	CYTOVALE, INC.	2014	NHLBI	NHLBI	$225,000	View
	5	Robust High-throughput Mechanical Phenotyping Platform for Clinical Diagnostics R43TR000351-02			TSE, HENRY	CYTOVALE, INC.	2014	NCATS	NCATS	$199,720	View
	1	Robust High-throughput Mechanical Phenotyping Platform for Clinical Diagnostics R43TR000351-01A1			TSE, HENRY	CYTOVALE, INC.	2013	NCATS	NCATS	$199,999	View

[NIH RePORT, search results, accessed 4/16/25]

Cytovale Partnered With The Biomedical Advanced Research And Development Authority (BARDA) To Develop A Sepsis Diagnostic Test Beginning In 2018 And Ending In 2023, After Which The Device Received FDA Approval. "At BARDA, we are excited about the U.S. Food and Drug Administration (FDA) 510(k) clearance (2.99KB) of a host-based sepsis diagnostic, the IntelliSep test, developed by our partner Cytovale. This decision marks the 67th FDA approval/licensure/clearance for medical countermeasures supported by BARDA under novel public-private partnerships, as well as the first sepsis diagnostic BARDA has supported through regulatory approval… BARDA and Cytovale first partnered under the Solving Sepsis

program in November 2018 under the Division of Research, Innovation, and Ventures' (DRIVe's) Easy Broad Agency Announcement (EZ-BAA); the company received a follow-on contract with DRIVe in September 2019 to support clinical and regulatory activities for the advanced development of IntelliSep. This effort included execution of the CV-SQuISH-ED study, a multi-center clinical validation study to evaluate the performance of the IntelliSep, which was completed in early 2022." [BARDA, 2/23/23]

- **BARDA Paid Cytovale $749,000 Under Their Initial 2018 Agreement And $3.4 Million Under A 2019 Contract Development, Which Included Options To Provide An Additional $4.17 Million Over 2.5 Years Of Additional Work.** "To advance the development of a test that may be able to diagnose sepsis in less than 10 minutes, the U.S. Department of Health and Human Services (HHS) will partner with Cytovale of San Francisco. Under the cost-sharing agreement, the Biomedical Advanced Research and Development Authority (BARDA), part of the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), will provide expertise and $3.4 million to develop design specifications for the system and potentially an additional $4.17 million over 2.5 years for additional work, including studies needed to pursue regulatory clearance through the U.S. Food and Drug Administration (FDA)... The cost-sharing agreement announced today builds on work completed under a previous cost-sharing contract between Cytovale and BARDA's Division of Research Innovation and Ventures (DRIVe). BARDA provided $749,000 under that agreement through an EZ-BAA, or easy broad agency announcement." [BARDA via the Wayback Machine, 10/30/19]

Cytovale Reportedly Received Federal Funding From BARDA, The NIH, And NSF "To Support Technical And Clinical Development" Between 2019-2022.

[Cytovale, accessed 4/16/25]

As Of April 2025, Breakout Ventures Was Invested In Immusoft, A Medical Startup That Was Awarded Millions In NIH Funding Between 2012-2020 And Was Undergoing Clinical Trials In The U.S. As Of 2024

As Of April 2025, Breakout Ventures Was Invested In Immusoft.

[Breakout Ventures, accessed 4/16/25]

Immusoft Is A Medical Startup That "[Develops] Novel Cell Therapies By Programming B Cells TO Produce Therapeutic Proteins That Improve The Lives Of Patients With Rare Diseases." "Our mission at Immusoft is to develop novel cell therapies by programming B cells to produce therapeutic proteins that improve the lives of patients with rare diseases." [Immusoft, accessed 4/16/25]

Immusoft Was Awarded Millions In NIH Funding Between 2012-2020.

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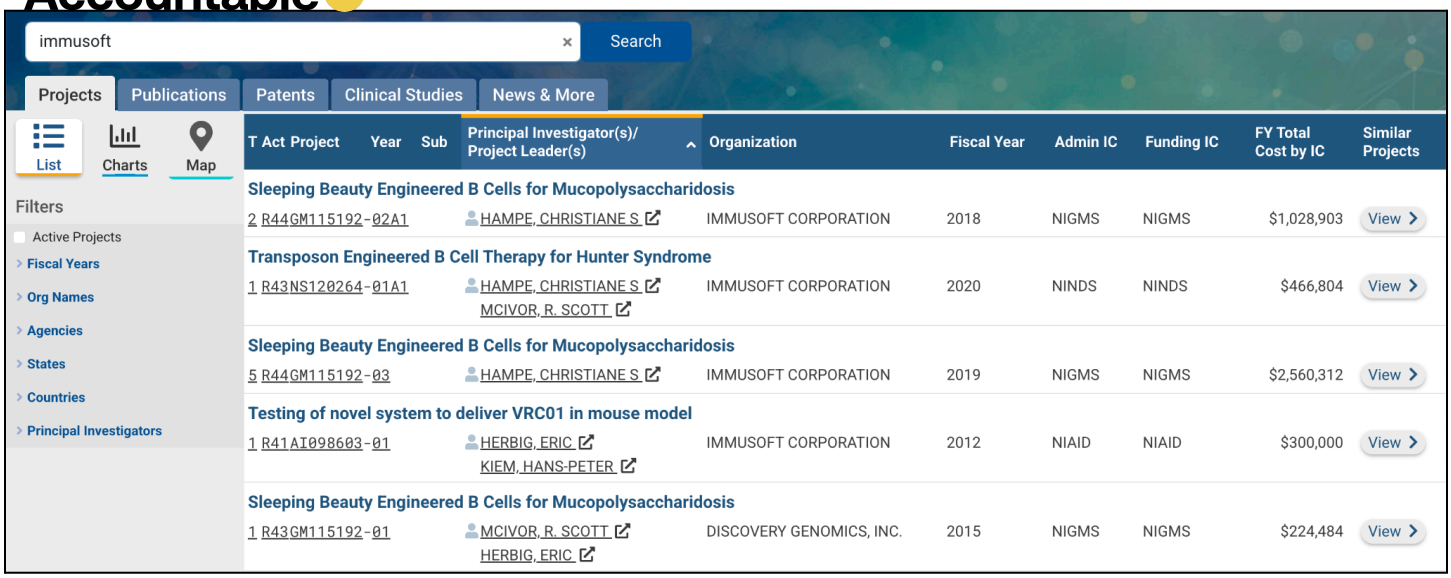

[NIH RePORT, search results, accessed 4/16/25]

Immusoft Was Undergoing Clinical Trials In The U.S. As Of 2024. "Immusoft of CA, a wholly owned subsidiary of Immusoft Corporation ("Immusoft"), a cell therapy company dedicated to improving the lives of patients with rare diseases, today announced positive results from the Phase 1 ISP-001 trial evaluating the therapy in a patient with mucopolysaccharidosis type I (MPS I). The clinical trial is supported by an $8 million award from the California Institute for Regenerative Medicine (CIRM), one of the world's largest institutes dedicated to regenerative medicine." [Immusoft, 9/23/24]

As Of April 2025, Breakout Ventures Was Invested In ShiraTronics, A Clinical-Stage Migraine Therapy Company That Builds Medical Devices Dependent On FDA Approval

As Of April 2025, Breakout Ventures Was Invested In ShiraTronics.

[Breakout Ventures, accessed 4/16/25]

ShiraTronics Is A Medical Device Company With Products Dependent On FDA Approval. "ShiraTronics is a privately held medical device company located in Minneapolis. Our seasoned team has developed a device that aims to combat debilitating chronic migraine disease." [ShiraTronics, accessed 4/16/25]

As Of 2024, ShiraTronics Was Clinical-Stage And Had Received FDA Approval For Trials. "ShiraTronics, a clinical-stage innovator in neuromodulation technology, today announced the initiation of its U.S. Food and Drug Administration (FDA) – approved Investigation Device Exemption (IDE) pivotal trial, the RELIEV-CM2 Clinical Study. The first implants of ShiraTronics neuromodulation therapy for Chronic Migraine have been completed in the United States and Australia, marking a new chapter in the company's efforts to develop innovative solutions for individuals impacted by this disabling condition." [ShiraTronics, 12/3/24]

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As Of April 2025, Breakout Ventures Was Invested In STRM.BIO, A Gene Therapy Startup That Was Awarded Millions In NIH Funding In 2022-2023

As Of April 2025, Breakout Ventures Was Invested In STRM.BIO.

[Breakout Ventures, accessed 4/16/25]

STRM.VIO Is A Pre-Clinical Biotechnology Gene Therapy Startup. "Based in Cambridge, MA, STRM.BIO is a pre-clinical, VC-backed biotechnology company that is leveraging extracellular vesicles (EVs) to deliver gene therapy in a better way: simpler, safer, practical. Our work will open the door to the future of medicine for patients living with rare diseases worldwide." [STRM.VIO, accessed 4/16/25]

STRM.BIO Was Awarded Millions Of Dollars In NIH Funding In 2022-2023.

[NIH RePORT, search results, accessed 4/16/25]

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