### UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

### FORM 8-K

### CURRENT REPORT

### Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 17, 2022

### VIVANI MEDICAL, INC.

(Exact name of registrant as specified in its charter)

California (State or other jurisdiction of incorporation) **001-36747** (Commission File Number)

**02-0692322** (IRS Employer Identification No.)

5858 Horton Street, Suite 280 Emeryville, California (Address of principal executive offices)

**94608** (Zip Code)

Registrant's telephone number, including area code: (818) 833-5000

(Former name or former address, if changed since last report.)

Chec	k the appropriate box below if the Form 8-K filing is intended	ded to simultaneously satisfy the filing obligation of	f the registrant under any of the following provisions:				
	Written communications pursuant to Rule 425 under the	Securities Act (17 CFR 230.425)					
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)						
	Pre-commencement communications pursuant to Rule 14	d-2(b) under the Exchange Act (17 CFR 240.14d-2	2(b))				
	Pre-commencement communications pursuant to Rule 13	e-4(c) under the Exchange Act (17 CFR 240.13e-4	(c))				
Secu	rities registered pursuant to Section 12(b) of the Act:						
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered				
	Common Stock Warrants	VANI VANIW	Nasdaq Capital Market				
	ate by check mark whether the registrant is an emerging greecurities Exchange Act of 1934 (§240.12b-2 of this chapter	1 2	ties Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of				
			Emerging growth company $\Box$				
	emerging growth company, indicate by check mark if the runting standards provided pursuant to Section 13(a) of the E		on period for complying with any new or revised financial				

#### Item 7.01. Regulation FD Disclosure

Vivani Medical, Inc. (the "Company"), will make presentations at the ThinkEquity Investor Conference described in item 8.01 below (the "Conference"). A copy of a slide presentation that Adam Mendelsohn, Chief Executive Officer and Brigid Makes, Chief Financial Officer intend to use (the "Presentation Materials") during the Conference is attached to this Current Report on Form 8-K as Exhibit 99.1, and is incorporated by reference herein. The Presentation Materials speak as of the date of this Current Report on Form 8-K. While the Company may elect to update the Presentation Materials in the future or reflect events and circumstances occurring or existing after the date of this Current Report on Form 8-K, the Company specifically disclaims any obligation to do so. The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by reference in such a filing.

#### Item 8.01 Other Events

The Company will present at the upcoming ThinkEquity investor conference at 11:00 am EDT at the Mandarin Oriental in New York on October 26, 2022. Dr. Adam Mendelsohn, CEO, will present a company overview and Brigid Makes, CFO, will join in hosting one-on-one meetings with investors during the conference. The presentation can be accessed live here: <a href="https://wsw.com/webcast/tep23/vani/1674436">https://wsw.com/webcast/tep23/vani/1674436</a>. A replay of the presentation will be available at www.vivani.com.

The Company issued a press release entitled *Vivani Medical to Present at the ThinkEquity Investor Conference*, which is attached to this Current Report as Exhibit 99.2.

#### Item 9.01 Financial Statements and Exhibits.

### (d) Exhibits.

Exhibit	

99.1 Presentation Materials Dated October 17, 2022

99.2 Press Release entitled Vivani Medical to Present at the ThinkEquity Investor Conference dated October 17, 2022.

The cover page of this Current Report on Form 8-K, formatted in Inline XBRL.

### SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

### VIVANI MEDICAL, INC.

Date: October 17, 2022

By: /s/ Donald Dwyer
Donald Dwyer
Chief Business Officer



# Vivani Medical, Inc.



SEC@NDSIGHT

combination of

Nano Precision Medical

and

Second Sight Medical Products

October 17, 2022

### **Disclaimers**

The following slides and any accompanying oral presentation contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are intended to be covered by the "safe harbor" created by words such as "estimates," "anticipates," "projects," "plans" or "planned," "strategy," "goal," "seeks," "may," "will," "expects," "intends," "believes," "should," and similar expressions, or the negative versions thereof, and which also may be identified by their context. All statements that address operating performance or events or developments that Vivani Medical, Inc. ("Vivani", the "Company", "we" or "us) expects or anticipates will occur in the future, such as stated objectives or goals, our product candidates and their therapeutic potential and planned development, the indications that we intend to target, our technology, our business and strategy, milestones, addressable markets, or that are not otherwise historical facts, are forward-looking statements included in this presentation on its current expectations, the information on which such expectations were based may change. Forward-looking statements involve inherent risks and uncertainties which could cause actual results to differ materially from those in the forward-looking statements are result of various factors. These risks and uncertainties include us are not limited to, that we may fail to complete any required preclinical activities for NPM-119 or otherwise commence our planned Phase 2 trial for this candidate; conduct any pre-clinical activities of our other product candidates; on product candidates may be inaccurate; we may aproval or changes in regulatory framework that are out of our control; our estimation of addressable markets of our product candidates may be inaccurate; we may fail to timely raise additional required funding; more efficient competitors or more effective competing treatment may emerge; we may be involved in disputes su

## **Vivani Executive Leadership Team**



### Adam Mendelsohn PhD - CEO/Director

- · Co-founder/Co-inventor of Nano Precision Medical technology
- PhD Bioengineering (UCSF/UC Berkeley)
- · Management of Technology Certificate at Haas School of Business
- · Research focused on diabetes treatment
- · Formerly at Boston Scientific and Minimed



### Truc Le, MBA - Chief Operations Officer

- · Numerous COO and Executive Positions at Device and Drug-
- Device Companies, including:
   COO at Dance Biopharm, COO at Avid Bio
   Exec VP at Prima Biomed, Sr. vP at Nektar Therapeutics (responsible for Exubera approval), and Worldwide VP at Johnson & Johnson



### Brigid Makes MBA - Chief Financial Officer

- Former Sr. VP and CFO Miramar Labs
- Former Sr. VP and CFO Malana Laus Former Sr. VP and CFO AGA Medical Former CFO Nektar Therapeutics, OraVax and Haemonetics Current Board director: Quantun-Si, Aziyo and Mind Medicine Involved in/Directed 2 IPOs, 2 reverse mergers and 1 SPAC



### Lisa Porter, MD - Chief Medical Officer

- · Former Chief Medical Officer for Eiger BioPharmaceuticals And Dance BioPharm
   Former VP of Medical Development for Amylin
   Former Director at GSK, Global Head of Clinical Strategy for

- Former Board member of ViaCyte, Inc.



### Don Dwyer, MBA - Chief Business Officer

- Former Executive Director at AstraZeneca with leadership roles in drug development, commercial and business development
  Former NPM Board observer for AZ
  Former PhaseBio Board observer for AZ
  Former PhaseBio Board observer for AZ (prior to IPO)
  Former Director at Cephalon and Rhone Poulenc Rorer



## Vivani Medical, Inc.

- An innovative, clinical-stage, biopharmaceutical company that develops and manufactures novel, long-term therapeutic implants to treat chronic diseases.
- Biopharm Division (formerly Nano Precision Medical) develops tiny, drug implants that provide therapeutic levels of medicine over extended periods of time, guaranteeing medication adherence. NPM-119 (6-month GLP-1 implant candidate for Type 2 Diabetes) is Vivani's main focus.
- Neuromodulation Division (formerly Second Sight Medical Products) develops highly innovative medical implant candidates to treat blindness. Vivani is assessing strategic options for advancing Orion II, a cortical visual prosthesis designed to treat profound blindness.
- Vivani is well-positioned with new leadership and sufficient capital to support multiple milestones for NPM-119 while assessing strategic options for Orion II.

# **Combined Company Pipeline**

If Approved, Vivani Candidates will Compete in Markets with Large Potential

	Indication	Feasibility	Pre-Clinical	Clinical	Market Size*
ia Ca	Human Type II Diabetes	NPM exenat	-119		>\$20B
Nano Precision Medical	Feline Pre- Diabetes & Diabetes	OKV-119**			>\$500M
no Precis	NASH (Non- Alcoholic Steatohepatitis)	NPM-159*** proprietary compound			>\$18B
S	Human Obesity	NPM-139*** proprietary compound			>\$19B
SSMP	Profound Blindness		RION al prosthesis		>\$1B

<sup>\*</sup> Estimated Market Sizes where Vivani candidates would compete, if approved; Does not represent future sales or revenue estimates of Vivani candidates
\*\* In Partnership with Okava Pharmaceuticals, Inc.
\*\*\* Feasibility in progress with a non-exenatide compound in collaboration with a major pharma company







Designed to Assure Adherence

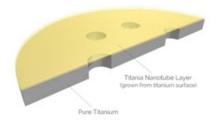


Minimally-fluctuating and tunable delivery profiles



Potential application with many molecular types





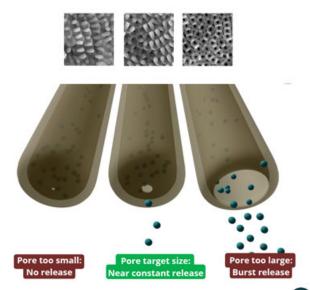




### NanoPortal:

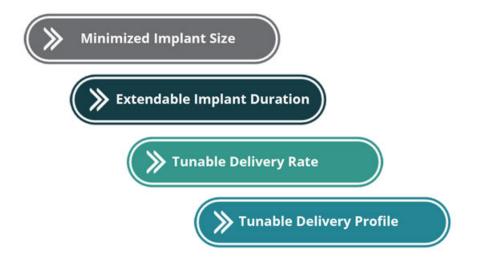
How it Works...

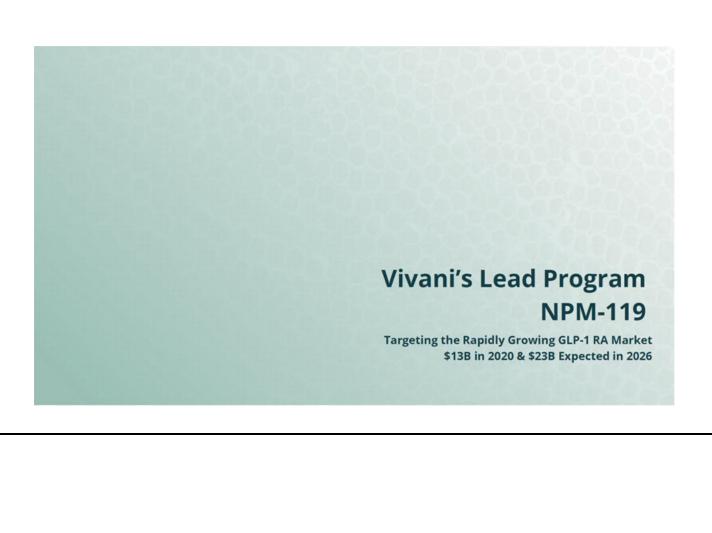
By precisely adjusting nanotubes to molecule size, interactions between drug and nanotube walls can result in desirable release profiles over time, including **near constant release** 



# NanoPortal™ is a Platform Technology

Broad Potential Application Can Support Portfolio of New Drug Implants





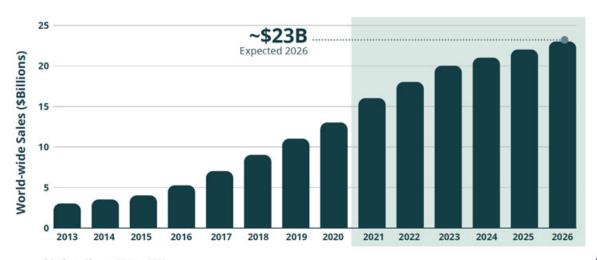
## Lead Product (NPM-119):

6-Month Exenatide (Glucagon-like Peptide 1 Receptor Agonist) Implant for Type 2 Diabetes

1 Guo 2016 2 Carls et al., 2017 3 MS 2013 Report

- Non-adherence is the primary reason for low, real-world effectiveness<sup>1,2</sup>
- Guaranteed adherence will produce significant healthcare cost savings<sup>3</sup>
- FDA indicated 505(b)(2) streamlined approval pathway may be available
- ~\$54M raised pre-merger from investors including AstraZeneca

# **GLP-1 Market Opportunity\***



\* Evaluate Pharma 08 June 2021

# **Current Drug Adherence Challenge**

"Drugs don't work in people that don't take them"

### NPM-119 Designed to Enable 100% Adherence through Implant Duration

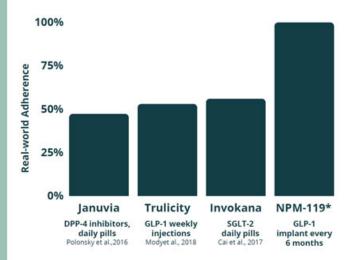
- · Orals and injectables do not guarantee adherence
- Approximately 50% of patients do not meet glycemic targets primarily due to adherence

# Dual Incentive to Adopt Technology that Improves Adherence

- · Pharmaceutical revenue is increased
- · Healthcare costs are decreased

\* NPM-119 - investigational candidate, not approved in any market

### Real-World Adherence of Select Drugs



\* NPM-119 designed to enable 100% adherence.

# Guaranteed adherence is expected to deliver improved health outcomes

Drug Substance + Administration = Drug Product

- Varying levels of adherence are associated with different health outcomes
- Different health outcomes may not be attributable to drug substance alone
- The American Diabetes Association (ADA) Standard of Care guidelines encourage treatment options that address adherence

\* NPM-119 - investigational candidate, not approved in any market

Drug Drug Administration Substance Product Weekly Injection exenatide BYDUREON\* (GLP-1 Receptor Agonist) Weekly Injection dulaglutide trulicity. (GLP-1 Receptor Agonist) Weekly Injection semaglutide injection 0.5mg 1mg semaglutide (GLP-1 Receptor Agonist) RYBELSUS\* Daily semaglutide tablets Pill

exenatide

(GLP-1 Receptor Agonist)

6-Month Implant

NPM-119\*



# Intarcia's ITCA 650 (6-month exenatide implant) may be a relevant value analog for NPM-119

### Value of long-term GLP-1 (exenatide) implant externally validated previously

**2014** – Intarcia signed ITCA 650 deal with Servier (excluding US + Japan) \$171M up-front, \$880M milestones, and double-digit royalties

Financings valued Intarcia as high as \$4.0B **(2017)** Intarcia's lead program was ITCA 650

- 2016 Intarcia filed initial ITCA 650 New Drug Application (NDA)
- 2017 FDA issued the first ITCA 650 CRL\* (cited manufacturing concerns)
- 2019 Intarcia re-submitted ITCA 650 NDA
- 2020 FDA issued second ITCA 650 CRL (cited clinical safety and device constituent concerns)
- 2022 After multiple dispute resolution actions, FDA denied Intarcia's request for public hearing

<sup>\*</sup> CRL: Complete Response Letter – issued by FDA to identify NDA deficiencies

# NPM-119 well-positioned to avoid Intarcia's device technology challenges

### Osmotic Pump (Intarcia)



- FDA has concerns about daily variations in release
- Larger Device (4mm x 45mm)
- Insertion using larger 6-gauge needle

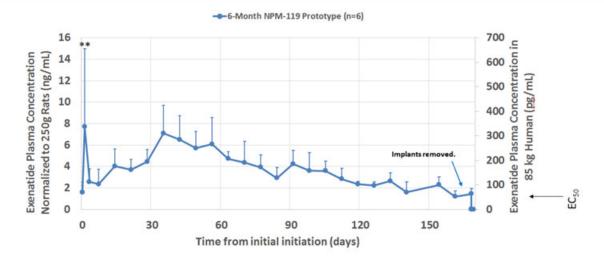
### NanoPortal™ (NPM)



- Minimally fluctuating release profile observed in pre-clinical studies
- Smaller Device (2.2mm x 21.5mm)
- Insertion using smaller 11-gauge needle



## 6-Month NPM-119 Preclinical Proof-of-Concept Achieved



<sup>\*</sup> Exenatide antibody-positive animals are not included in this data set.

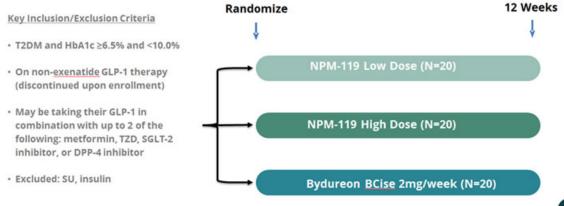
\*\*2 of 6 implants are responsible for higher Day 1 exenatide concentrations. Additional optimization ongoing to yield consistent gradual initial PK profiles.



## **Proposed First in Human Trial: LIBERATE-1**

Primary Objectives: Safety/tolerability assessment and full PK characterization

Secondary Objective: Evaluate change from baseline in glycemic control (HbA1c)



T2DM: Type 2 Diabetes Mellitus; TZD: Thiazolidinedione; SGLT-2: Sodium-glucose cotransporter-2; DPP-4: Dipeptidyl peptidase 4; SU: Sulfonylurea

## NPM-119 Clinical + Regulatory Development Near-Term Plan

Year(s)	Milestone	Status
2020	FDA Pre-IND Meeting	Completed
4Q2022 / 1Q2023	File IND to support Ph 2 (LIBERATE-1) clinical study	On-Track
2023	Deliver LIBERATE-1 top-line results	Projected

We expect to utilize the 505(b)(2) pathway, which permits submissions to rely, in part, on the safety and effectiveness of a previously approved product, which may potentially result in a more expeditious pathway to FDA approval.

Progress towards IND-enabling activities:

- · Development of both low dose and high dose versions of NPM-119 to be used in LIBERATE-1 is complete
- · Recent extensive studies have confirmed excellent biocompatibility of NPM-119's device constituent
- · NPM-119 was well tolerated in a preclinical GLP toxicology study
- · GMP production of LIBERATE-1 clinical supplies is underway





### **Orion II**

# **Current Activities and Future Considerations**

- Initial clinical pilot study at UCLA and Baylor College of Medicine; 3-year data encouraging
- · Confirming regulatory pathway with FDA
- Patient Preference Study Part one informs potential adoption; encouraging results obtained
- Patient Preference Study Part two defines safety endpoints for approval; in preparation
- Market Access, Reimbursement and Long-term Support Programs critical for long-term success
- New Leadership Team is developing strategic options for advancing Orion II



### Vivani Medical, Inc. Pro-Forma P&L Statement

		Histo	orical		Pr	o forma	P	ro forma
in 000s)	Second Sight		NPM		adjustments		combined	
or the six months ended June 30, 2022:								
Net sales	\$		\$		\$		5	
Cost of sales								
Gross profit								-
Total operating expenses		5,345		7,995		(1,615)		11,725
Loss from operations	\$	(5,345)	\$	(7,995)	\$	1,615	\$	(11,725
Loss per share on a pro forma basis							\$	(0.23
or the year ended December 31, 2021:								
Net sales	\$		\$		\$		\$	
Gross profit		130						13
Total operating expenses		9,063		13,323		2,154		24,540
Loss from operations	\$	(8,933)	\$	(13,323)	\$	(2,154)	\$	(24,410

(The unaudited pro forma condensed combined financial information was derived from, and should be read in conjunction with, the Exhibit 99.3 included in Form 8-K filed with the SEC on September 2, 2022)

## Vivani Medical, Inc. Pro-forma Balance Sheet

(\$ in 000s)							Co	ombined
For the Period ending June 30, 2022		cond Sight distorical	н	NPM istorical	ac	Merger ljustments		o forma adjusted
Assets		12	100					
Cash and cash equivalents	\$	56,377	\$	3,450	S	(1.624)	S	58,203
Other assets		9,272		2,967		(8,000)		4,239
Total assets	S	65,649	S	6,417	S	(9,624)	S	62,442
Liabilities and Stockholders' equity								
Current liabilities	5	2,591	5	2,905	S	(984)	S	4,512
SAFE				8,000		(8,000)		-
Long-term liabilities		-		328		-		328
Total liabilities		2,591		11,233	_	(8,984)		4,840
Stockholders' Equity								
Common stock and APIC		397,355		62,109		(340,080)		119,384
Other comprehensive income		(424)				424		
Accumulated deficit		(333,873)		(66,925)		339,016		(61,782)
Total equity		63,058		(4,816)		(640)		57,602
Total liabilities and equity	5	65,649	S	6,417	S	(9,624)	5	62,442

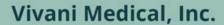
(The unaudited pro forma condensed combined financial information was derived from, and should be read in conjunction with, the Exhibit 99.3 included in Form 8-K filed with the SEC on September 2, 2022)

## Vivani Medical, Inc. Post Merger Cap Table

	Name
Tota	Shares Outstanding
	Restricted Shares (Locked- 80 Days)
Unre	stricted Shares

100	Capitalizat	ion Table	
Common (CS)	Options Outstanding (1)	Common Warrants (2)	Total Shares, Options & Warrants
50,726,329	4,609,642	10,310,539	65,646,510
21,942,231	2,214,791	9,310,573	33,467,598
28,784,098	2,394,850	999,966	32,178,918
43.3%	48.0%	90.3%	51.0

- (1) 795K outstanding stock options unvested
- (2) 2.564M Common Warrants underwater and expire March 2024.



- An innovative, clinical-stage, biopharmaceutical company that develops and manufactures novel, long-term therapeutic implants to treat chronic diseases.
- Biopharm Division (formerly Nano Precision Medical) develops tiny, drug implants that provide therapeutic levels of medicine over extended periods of time, guaranteeing medication adherence. NPM-119 (6-month GLP-1 implant candidate for Type 2 Diabetes) is Vivani's main focus.
- Neuromodulation Division (formerly Second Sight Medical Products) develops highly innovative medical implant candidates to treat blindness. Vivani is assessing strategic options for advancing Orion II, a cortical visual prosthesis designed to treat profound blindness.
- Vivani is well-positioned with new leadership and sufficient capital to support multiple milestones for NPM-119 while assessing strategic options for Orion II.



#### Vivani Medical to Present at the ThinkEquity Investor Conference

EMERYVILLE, Calif. – (BUSINESS NEWSWIRE) – Oct. 17, 2022 – Vivani Medical, Inc. (NASDAQ: VANI) (the "Company" or "Vivani"), an innovative, clinical-stage biopharmaceutical company that develops novel, long-term therapeutic implants, announced today that it will present at the upcoming ThinkEquity investor conference at 11:00 am EDT at the Mandarin Oriental in New York on October 26, 2022.

Dr. Adam Mendelsohn, CEO, will present a company overview and Brigid Makes, CFO, will join in hosting one-on-one meetings with investors during the conference.

The presentation can be accessed live here: <a href="https://wsw.com/webcast/tep23/yani/1674436">https://wsw.com/webcast/tep23/yani/1674436</a>. A replay of the presentation will be available at www.vivani.com.

About Vivani Medical, Inc.

Leveraging its proprietary NanoPortal platform, Vivani Medical develops biopharmaceutical implants designed to deliver drug molecules steadily over extended periods of time, with the goal of guaranteeing patient adherence to their medication. Vivani's lead program, NPM-119, is a tiny, 6-month GLP-1 implant under investigation for the treatment of patients with Type 2 diabetes. NPM-119 can provide patients the opportunity to realize the full potential benefit of their medication while avoiding the hassles associated with the daily or weekly administration of oral and injectable products. Medication non-adherence occurs when patients do not take their medication as prescribed. This affects an alarming number of patients, approximately 50%, including those taking daily pills. Medication non-adherence is a primary reason why Type 2 diabetes treatments face significant challenges in achieving positive real-world effectiveness.

Vivani represents the August 2022 merger of Second Sight Medical Products, Inc., and Nano Precision Medical, Inc. NPM-119 is being developed within Vivani's Biopharm Division (formerly Nano Precision Medical, Inc.). An IND for NPM-119 remains on track for filing around the end of this year to support initiation of a Phase 2 clinical study called LIBERATE-1. Vivani is also developing a portfolio of innovative, highly differentiated, new drug product candidates leveraging its proprietary NanoPortal implant technology, which has potential application across a broad range of compounds.

Vivani's Neuromodulation Division (formerly Second Sight Medical Products) has developed, manufactured, and marketed implantable visual prosthetics that are intended to deliver useful artificial vision to blind individuals. Vivani is currently assessing strategic options for advancing Orion II, a visual prosthetic device designed to treat profound blindness.

#### Forward-Looking Statements

This press release contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the US Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that in this press release, including statements regarding our business, product candidates, including the therapeutic potential thereof and the planned development therefor, technology and strategy. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results and outcomes to differ materially from those indicated in the forward-looking statements include, among others, risks related to the development and commercialization of our product candidates, including NPM-119; delays and changes in applicable laws, regulations and guidelines including potential delays in submitting required regulatory applications to the U.S. Food and Drug Administration ("FDA"); risks related to the initiation, enrollment and conduct of our planned clinical trials and the results therefrom; our history of losses and our ability to achieve or sustain profitability in the future; and the impact of COVID-19 on our business. There may be additional risks that the Company considers immaterial, or which are unknown. A further list and description of risks and uncertainties can be found in the Company's most recent Annual Rep

Company Contact: Don Dwyer Chief Business Officer info@vivani.com (818) 833-5000

Investor Relations Contact: Brigid Makes Chief Financial Officer investors@vivani.com (818) 833-5000

Media Contact: Sean Leous ICR Westwicke Sean.Leous@westwicke.com (646) 866-4012