# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## Schedule 13D

(Rule 13d-101)

INFORMATION TO BE INCLUDED IN STATEMENTS FILED PURSUANT TO RULE 13d-1(a) AND AMENDMENTS THERETO FILED PURSUANT TO RULE 13d-2(a)

**Under the Securities Exchange Act of 1934** 

# Neovasc, Inc.

(Name of Issuer)

Common Shares, No Par Value (Title of Class of Securities)

> 64065J205 (CUSIP Number)

Kate Inman, Esq. General Counsel and Secretary OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137 (305) 575-4100

Phillip Frost, M.D.
Frost Gamma Investments Trust
4400 Biscayne Blvd, Suite 1500
Miami, Florida 33137
(305) 575-6015
(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

June 12, 2019 (Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Schedule 13G to report the acquisition that is the subject of this Schedule 13D, and is filing this schedule because of Rule 13d-1(e), 13d-1(f) or 13d-1(g), check the following box.  $\Box$ 

Note: Schedules filed in paper format shall include a signed original and five copies of the schedule, including all exhibits. See Rule13d-7 for other parties to whom copies are to be sent.

The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

(Continued on following pages)

<sup>\*</sup> The remainder of this cover page shall be filled out for a reporting person's initial filing on this form with respect to the subject class of securities, and for any subsequent amendment containing information which would alter disclosures provided in a prior cover page. The information required on the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Notes).

1	NAME OF R	EPOR	TING PERSON	
	OPKO Health, Inc.			
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	(a) 🗵 (b)	$\boxtimes$		
3	SEC USE ON	IV		
3				
4	4 SOURCE OF FUNDS			
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5	WC 5 CHECK BOX IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO ITEMS 2(D) OR 2(E)			
3	5 CHECK BOA IF DISCLOSURE OF LEGAL PROCEEDINGS IS REQUIRED PURSUANT TO HEMS 2(D) OR 2(E)			
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12	3,385,753 (1)  CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES			
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14	TYPE OF RE	POR'	TING PERSON	
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- Comprised of 3,385,753 shares of common stock, no par value (the 'Common Stock'), of Neovasc Inc. (the "<u>Issuer</u>"). Calculated based on 67,475,883 shares of Common Stock outstanding as of May 2, 2019, as reported by the Issuer in its Information Circular furnished to the Securities and Exchange Commission on Form 6-K on May 29, 2018 (the "<u>Form 6-K</u>").

1	NAME OF REPORTING PERSON			
	Phillip Frost, M.D.			
2			ROPRIATE BOX IF A MEMBER OF A GROUP	
	(a) 🗵 (b)	$\times$		
3	SEC USE ON	LY		
4	SOURCE OF	FUN:	DS	
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	WITH	10	SHARED DISPOSITIVE POWER	
			SHARED DISPOSITIVE FOWER	
			1,165,147 (1)	
11	AGGREGAT	E AM	OUNT BENEFICIALLY OWNED BY EACH REPORTING PERSON	
	1,165,147 (1)			
12				
13	3 PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)			
	1.7% (2)			
14	TYPE OF RE	PORT	TING PERSON	
	IN			

<sup>(1)</sup> Includes 1,165,147 shares of Common Stock held by Frost Gamma Investments Trust. Dr. Phillip Frost is the trustee of Frost Gamma Investments Trust.

<sup>(2)</sup> Calculated based on 67,475,883 shares of the Common Stock outstanding as of May 2, 2019.

1	NAME OF REPORTING PERSON			
	Frost Gamma Investments Trust			
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		$\times$		
	.,			
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	Florida			
		7	SOLE VOTING POWER	
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		10	SHARED DISPOSITIVE FOWER	
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	1 165 147 (1)			
10	1,165,147 (1)			
12	12 CHECK BOX IF THE AGGREGATE AMOUNT IN ROW (11) EXCLUDES CERTAIN SHARES			
13	PERCENT OF CLASS REPRESENTED BY AMOUNT IN ROW (11)			
	1.7% (2)			
14	TYPE OF RE	PORT	TING PERSON	
	00			
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<sup>(1)</sup> Includes 1,165,147 shares of Common Stock held by Frost Gamma Investments Trust. Dr. Phillip Frost is the trustee of Frost Gamma Investments Trust.

<sup>(2)</sup> Calculated based on 67,475,883 shares of the Common Stock outstanding as of May 2, 2019.

#### EXPLANATORY NOTE

This Schedule 13D is filed (i) by Phillip Frost, M.D. and Frost Gamma Investments Trust (<u>\*FGIT</u>") and (ii) by OPKO Health, Inc. (<u>\*OPKO</u>") to amend and restate the Schedule 13G filed by OPKO on February 14, 2017, as amended on February 14, 2018 and February 14, 2019.

On September 7, 2018, the Securities and Exchange Commission (the "SEC") filed a civil complaint in the Southern District of New York (the "Complaint"), against a number of individuals and entities, including OPKO and its CEO and Chairman, Dr. Frost.

In December 2018, OPKO, Dr. Frost and FGIT entered into settlements with the SEC, which, upon approval by the court in January 2019, resolved the claims against OPKO, Dr. Frost and FGIT. Pursuant to the settlement between OPKO and the SEC, and without admitting or denying any of the allegations of the Complaint, OPKO agreed to be enjoined from future violations of Section 13(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), a claim that requires no showing of scienter, and to pay a civil monetary penalty, which has been paid. OPKO also agreed, within certain stipulated time periods, to: (i) establish a Management Investment Committee ("MIC") that will make recommendations to an Independent Investment Committee ("IIC") of OPKO's board of directors in connection with existing and future strategic minority investments; and (ii) retain an Independent Compliance Consultant ("ICC") on a time-limited basis to, among other things, advise OPKO on whether filings pursuant to Section 13(d) of the Exchange Act for previous strategic minority investments made at the suggestion of or in tandem with Dr. Frost and his related persons or entities should be made or amended to reflect group membership with Dr. Frost.

Under the terms of the settlement between the SEC, Dr. Frost and FGIT, and without admitting or denying any of the allegations in the Complaint, Dr. Frost agreed to injunctions from violations of Sections 5(a) and (c) and 17(a)(2) of the Securities Act of 1933, claims which may be satisfied by strict liability and negligence, respectively, and Section 13(d) of the Exchange Act, also a strict liability claim; to pay a civil monetary penalty, disgorgement and pre-judgment interest, which have been paid; and to be prohibited, with certain exceptions, from trading in penny stocks.

The ICC has concluded his work. The ICC determined that certain prior investments by OPKO and Dr. Frost with respect to other issuers should have been grouped under Section 13(d) of the Exchange Act and that amended filings under Section 13(d) of the Exchange Act should be made. OPKO and Dr. Frost made the recommended filings on May 9, 2019. The ICC did not recommend any additional filings in connection with the Issuer. However, because of the relationship between Dr. Frost and OPKO, the Reporting Persons have elected to make such filings with respect to certain additional issuers, including the Issuer.

OPKO has now established the MIC and IIC, and following the establishment of these committees, any group between OPKO and Dr. Frost with respect to investments in the Issuer has ceased to exist.

#### ITEM 1. SECURITY AND ISSUER

This statement on Schedule 13D relates to the common stock, no par value (the 'Common Stock'), of Neovasc Inc., a Canadian corporation (the "Issuer"). The principal executive offices of the Issuer are located at: Suite 5138 — 13562 Maycrest Way, Richmond, British Columbia, Canada V6V 2J7.

#### ITEM 2. IDENTITY AND BACKGROUND

Set forth in Schedule 1 to this Schedule 13D are the name, business address and present principal occupation or employment and citizenship of each executive officer and director of OPKO and FGIT.

- (a), (f) This statement is being filed by:
- (i) OPKO, a corporation incorporated under the laws of the State of Delaware;
- (ii) Phillip Frost, M.D.; and
- (iii) FGIT, a trust organized under the laws of the State of Florida.

The Reporting Persons have entered into a joint filing agreement, dated as of June 12, 2019, a copy of which is attached hereto as Exhibit 1.

- (b) The address of the principal business and principal office of OPKO is 4400 Biscayne Blvd., Miami, Florida 33137. The address of the principal business and principal office of Dr. Frost and FGIT is 4400 Biscayne Blvd., Suite 1500, Miami, Florida 33137.
- (c) OPKO is a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Dr. Frost's principal occupation is serving as Chairman and Chief Executive Officer of OPKO. The principal business of FGIT is to invest in securities. Dr. Frost is the sole trustee of FGIT. Frost Gamma Limited Partnership is the sole and exclusive beneficiary of FGIT.
- (d), (e) The information set forth under the heading "Explanatory Note" above is incorporated herein by reference in its entirety to this Item 2(d) and Item 2(e). Except as disclosed above under the heading "Explanatory Note," during the last five years, none of the Reporting Persons or any of the persons listed on Schedule I hereto (i) has been convicted in a criminal proceeding (excluding traffic violations or similar misdemeanors) or (ii) was a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to, federal or state securities laws or finding any violations with respect to such laws.

#### ITEM 3. SOURCE AND AMOUNT OF FUNDS OR OTHER CONSIDERATION

The information set forth or incorporated under the heading "Explanatory Note" and in Items 4 and 5 is incorporated by reference in its entirety into this Item 3

On August 16, 2011, OPKO entered into an agreement to provide consulting services (the <u>Consulting Agreement</u>") to the Issuer. As compensation for services under that agreement, the Issuer granted OPKO options to purchase 913,750 shares of Common Stock. The Issuer granted OPKO additional options for the acquisition of 86,250 shares of Common Stock on August 16, 2012. OPKO exercised its stock options on November 28, 2017. The source of funds used by OPKO for each of its other acquisitions of securities of the Issuer was working capital or the exchange, exercise or conversion of securities of the Issuer of the Issuer previously acquired by OPKO.

The source of funds used by FGIT for each of its acquisitions of securities of the Issuer and its predecessors was working capital of FGIT.

#### ITEM 4. PURPOSE OF TRANSACTION

The information set forth or incorporated under the heading "Explanatory Note" and in Items 2, 3 and 5 is incorporated by reference in its entirety into this Item 4.

Steven D. Rubin, who serves as Executive Vice President – Administration and a director of OPKO, is a director of the Issuer. Dr. Jane Hsiao, who serves as the Vice-Chairman and Chief Technical Officer of OPKO, is a director of the Issuer.

Each of the Reporting Persons may, at any time or from time to time, formulate plans or proposals regarding the Issuer or its securities to the extent deemed advisable by the Reporting Persons in light of each of their general investment policies, market conditions, subsequent developments affecting the Issuer, the general business and future prospects of the Issuer, or other factors. The Reporting Persons intend to review their investments in the Issuer on a continuing basis. Depending on various factors, including, without limitation, the Issuer's financial position and strategic direction, actions taken by the board of directors, price levels of shares of the Common Stock, other investment opportunities available to the Reporting Persons, concentration of positions in the portfolios managed by the Reporting Persons, market conditions and general economic and industry conditions, the Reporting Persons may in the future take such actions with respect to their investments in the Issuer as they deem appropriate, including, without limitation, purchasing additional shares of the Common Stock or other financial instruments related to the Issuer or selling some or all of their beneficial or economic holdings, engaging in hedging or similar transactions with respect to the securities relating to the Issuer and/or otherwise changing their intention with respect to any and all matters referred to in Item 4 of Schedule 13D.

Except as disclosed herein, none of the Reporting Persons has any plans or proposals which relate to or which would result in any of the actions specified in this paragraph of Item 4 of Schedule 13D.

#### ITEM 5. INTEREST IN SECURITIES OF THE ISSUER

(a) (b) The information contained in rows 7, 8, 9, 10, 11 and 13 on each of the cover pages of this Schedule 13D and the information set forth or incorporated in Items 2, 3, 4 and 6 is incorporated by reference in its entirety into this Item 5.

Dr. Frost is the trustee of FGIT. Frost Gamma Limited Partnership is the sole and exclusive beneficiary of FGIT. Dr. Frost is one of two limited partners of Frost Gamma Limited Partnership. The general partner of Frost Gamma Limited Partnership is Frost Gamma, Inc. and the sole shareholder of

Frost Gamma, Inc. is Frost-Nevada Corporation. Dr. Frost is the sole shareholder of Frost-Nevada Corporation. As a result of the foregoing, Dr. Frost is also considered beneficial owner of the securities owned by FGIT. Dr. Frost disclaims beneficial ownership in the securities except to the extent of any pecuniary interest therein.

The following persons named in Item 2, other than the Reporting Persons, beneficially own securities of the Issuer:

	Number of Shares of Common Stock Beneficially		Sole or Shared Dispositive	
Name	Owned	Sole or Shared Voting Power	Power	Percentage of Class
Jane H. Hsiao, Ph.D., MBA	176,386 (1)	Sole	Sole	<1% (2)
Steven D. Rubin	152,686 (3)	Sole	Sole	<1% (2)

- (1) Comprised of (i) 7,912 shares of Common Stock owned directly by Dr. Hsiao (ii) 17,857 shares of Common Stock owned by Hsu Gamma Investment, L.P., of which Dr. Hsiao is the general partner, and (iii) 150,617 shares of Common Stock issuable upon exercise of exercisable stock options. Excludes 150,333 shares of Common Stock issuable upon exercise of exercisable stock options that are not currently exercisable. The stock options were received as a result of Dr. Hsiao's service as a director of the Issuer.
- Dr. Hsiao disclaims beneficial ownership of shares of Common Stock owned by Hsu Gamma Investment, L.P., except to the extent of any pecuniary interest therein and this report shall not be deemed an admission that the reporting person is the beneficial owner of the securities for purposes of Section 16 or for any other purpose.
- (2) Based on 67,475,883 shares of Common Stock outstanding as of May 2, 2019, as reported by the Issuer in its Information Circular furnished to the Securities and Exchange Commission on Form 6-K on May 29, 2019 and 150,617 shares of Common Stock issuable upon exercise of exercisable stock options.
- (3) Comprised of (i) 2,069 shares of Common Stock, and (ii) 150,617 shares of Common Stock issuable upon exercise of exercisable stock options. Excludes 150,333 shares of Common Stock issuable upon exercise of exercisable stock options that are not currently exercisable.
- OPKO's reported ownership does not include securities beneficially owned by FGIT, Dr. Frost, Mr. Rubin and Dr. Hsiao. OPKO disclaims beneficial ownership of the securities of the Issuer owned by FGIT, Dr. Frost Dr. Hsiao and Mr. Rubin.
- Dr. Frost and FGIT's reported ownership does not include securities owned by OPKO. In addition to serving as Chairman and Chief Executive Officer of OPKO, Dr. Frost and entities controlled by Dr. Frost (including FGIT) beneficially own approximately 35% of the outstanding common stock of OPKO. Dr. Frost and FGIT each disclaim beneficial ownership of the securities of the Issuer owned by OPKO.
- (c) There have been no transactions in shares of the Common Stock effected by any Reporting Person or any of the other persons named in Item 2 in the last 60 days.
- (d) No other person is known to the Reporting Persons to have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, the shares of the Common Stock covered by this Schedule 13D.
  - (e) Not applicable.

# ITEM 6. CONTRACTS, ARRANGEMENTS, UNDERSTANDINGS OR RELATIONSHIPS WITH RESPECT TO SECURITIES OF THE ISSUER

The information set forth or incorporated under the heading "Explanatory Note" and in Items 2, 3, 4 and 5 is incorporated by reference in its entirety into this Item 6.

Except for the matters described herein, the Reporting Persons do not have any contract, arrangement, understanding or relationship (legal or otherwise) with any person with respect to the securities of the Issuer.

#### ITEM 7. MATERIAL TO BE FILED AS EXHIBITS

Exhibit 1 Joint Filing Agreement

Exhibit 2 Power of Attorney

### **SIGNATURES**

After reasonable inquiry and to the best of each of the undersigned's knowledge and belief, each of the undersigned certify that the information set forth in this statement is true, complete and correct.

Date: June 12, 2019

OPK	OPKO Health, Inc.				
By:	/s/ Kate Inman				
	Kate Inman				
	General Counsel, Secretary				
	Dr. Phillip Frost				
By:	*				
Fros	at Gamma Investments Trust				
By:	*				
	Phillip Frost, M.D.				
	Trustee				

\* This Schedule 13D was executed by Steven D. Rubin on behalf of the individuals listed above pursuant to a Power of Attorney, a copy of which is attached as Exhibit 2.

By: /s/ Steven D. Rubin Attorney-in-Fact

## EXHIBIT INDEX

Exhibit

1 Joint Filing Agreement.
2 Power of Attorney.

# SCHEDULE 1

Directors of Opko Name	Business Address	Principal Occupation or Employment	Citizenship
Phillip Frost, M.D	4400 Biscayne Blvd., Suite 1500, Miami, Florida 33137	Chairman & Chief Executive Officer OPKO Health, Inc.	United States
Jane H. Hsiao, Ph.D., MBA	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Vice Chairman & Chief Technical Officer OPKO Health, Inc.	United States
Steven D. Rubin	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Executive Vice President –Administration OPKO Health, Inc.	United States
Robert S. Fishel, M.D.	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Chief Executive Officer & President Florida Electrophysiology Associates	United States
Richard M. Krasno, Ph.D.	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Lead Independent Director of Ladenburg Thalmann Financial Services, Inc.	United States
Richard A. Lerner, M.D.	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Institute Professor The Scripps Research Institute	United States
John A. Paganelli	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Chairman of the Board Pharos Systems International	United States
Richard C. Pfenniger, Jr.	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Former Chairman, Chief Executive Officer and President Continucare Corporation	United States
Alice Lin-Tsing Yu, M.D., Ph.D.	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Professor in Pediatrics at University of California in San Diego	United States

Executive Officers of Opko Name	Business Address	Principal Occupation or Employment	Citizenship
Phillip Frost, M.D	4400 Biscayne Blvd., Suite 1500, Miami, Florida 33137	Chief Executive Officer & Chairman of the Board.	United States
Jane H. Hsiao, Ph.D., MBA	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Vice Chairman & Chief Technical Officer.	United States
Steven D. Rubin	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Executive Vice President – Administration.	United States
Adam Logal	c/o OPKO Health, Inc. 4400 Biscayne Blvd. Miami, Florida 33137	Senior Vice President, Chief Financial Officer, Chief Accounting Officer and Treasurer.	United States

#### JOINT FILING AGREEMENT

In accordance with Rule 13d-1(k)(1) under the Securities Exchange Act of 1934, as amended, each of the undersigned hereby agrees to the joint filing, along with all other such undersigned, on behalf of the Reporting Persons (as defined in the joint filing), of a statement on Schedule 13D (including amendments thereto) with respect to Neovasc Inc. and that this agreement be included as an Exhibit 1 to such joint filing. This agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument. The undersigned acknowledge that each shall be responsible for the timely filing of any amendments, and for the completeness and accuracy of the information concerning him or it contained herein and therein, but shall not be responsible for the completeness and accuracy of the information concerning the others, except to the extent that he or it knows or has reason to believe that such information is inaccurate.

[Signature Page Follows]

IN WITNESS WHEREOF, each of the undersigned hereby executes this agreement as of June 12, 2019.

By: /s/ Kate Inman
Kate Inman
General Counsel, Secretary
Dr. Phillip Frost
By: *
Frost Gamma Investments Trust
By: *
Phillip Frost, M.D. Trustee

By: /s/ Steven D. Rubin

OPKO Health, Inc.

Attorney-in-Fact

\* This Schedule 13D was executed by Steven D. Rubin on behalf of the individuals listed above pursuant to a Power of Attorney, a copy of which is attached as Exhibit 2.

#### POWER OF ATTORNEY

The undersigned hereby constitutes and appoints Steven D. Rubin, with full power to act singly, his true and lawfulattorney-in-fact to: (i) sign any and all instruments, certificates and documents that may be necessary, desirable or appropriate to be executed on behalf of himself as an individual or in his capacity as a general partner of any partnership or limited liability company, pursuant to Section 13 or 16 of the Securities Exchange Act of 1934, as amended, and any and all regulations promulgated thereunder, (ii) file the same (including any amendments thereto), with all exhibits thereto, and any other documents in connection therewith, with the Securities and Exchange Commission, and any stock exchange or similar authority and (iii) take any other action of any type whatsoever in connection with the foregoing which, in the opinion of such attorney-in-fact, may be of benefit to, in the best interest of, or legally required by, the undersigned, it being understood that the documents executed by such attorney-in-fact on behalf of the undersigned pursuant to this power of attorney shall be in such form and shall contain such terms and conditions as such attorney-in-fact may approve in such attorney-in-fact's discretion, granting unto saidattorney-in-fact full power and authority to do and perform each and every act and thing necessary, desirable or appropriate.

The undersigned hereby grants to the attorney-in-fact full power and authority to do and perform any and every act and thing whatsoever requisite, necessary or proper to be done in the exercise of any of the rights and powers herein granted, as fully to all intents and purposes as the undersigned might or could do if personally present with full power of substitution or revocation, hereby ratifying and confirming all that such attorney-in-fact or such attorney-in-fact's substitute or substitutes, shall lawfully do or cause to be done by virtue of this power of attorney and the rights and powers herein granted.

This power of attorney shall remain in full force and effect until revoked by the undersigned in a signed writing delivered to theattorney-in-fact.

IN WITNESS WHEREOF, this Power of Attorney has been signed as of the 12th day of June, 2019.

Phillip Frost, M.D.

By: /s/ Phillip Frost, M.D.