CORINDUS VASCULAR ROBOTICS, INC.

FORM 8-K
(Current report filing)

Filed 01/08/18 for the Period Ending 01/08/18

Address
309 WAVERLEY OAKS ROAD
SUITE 105
WALTHAM, MA, 02452

Telephone 508-653-3335
CIK 0001528557
Symbol CVRS
SIC Code 3841 - Surgical and Medical Instruments and Apparatus
Industry Advanced Medical Equipment & Technology
Sector Healthcare
Fiscal Year 12/31
Date of Report (Date of earliest event reported): January 8, 2018

CORINDUS VASCULAR ROBOTICS, INC.
(Exact Name of Registrant as Specified in its Charter)

309 Waverley Oaks Road, Suite 105
Waltham, MA 02452
(Address of Principal Executive Office) (Zip Code)

Registrant's telephone number, including area code: (508) 653-3335

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2 below):

☐ 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 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth Company as defined in Rule 405 of the Securities Act of 1933 (§ 230-405 of this chapter) or Rule 12v-2 of the Securities Exchange Act of 1934 (§240.12v-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, individual by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Item 7.01    Regulation FD Disclosure.

Corindus Vascular Robotics, Inc. is furnishing as Exhibit 99.1 to this Current Report on Form 8-K an investor presentation which will be used, in whole or in part, and subject to modification, on January 8, 2018 and at subsequent meetings with investors or analysts.

The information in this Current Report on Form 8-K (including the exhibit) is being furnished pursuant to Item 7.01 of Form 8-K and shall not be deemed to be “filed” for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor will any of such information or exhibits be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01.    Financial Statements and Exhibits.

(d) Exhibits.

<table>
<thead>
<tr>
<th>Exhibit Number</th>
<th>Description</th>
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SIGNATURES

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

Date: January 8, 2018

CORINDUS VASCULAR ROBOTICS, INC.

By:  /s/ David W. Long

David W. Long
Chief Financial Officer
Corindus Vascular Robotics (CVRS) January 2018
Forward Looking Statements

This presentation contains “forward-looking statements” (as such term is defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended), and information relating to the company, that are based on the current beliefs of, and assumptions made by our management and the information currently available to our management. Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict,” “opinion,” “will” and similar expressions and their variants, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to statements related to our expected business, products, adoption of robotic medical procedures, results of operations, future financial condition, ability to increase our revenues, and similar matters. These forward-looking statements should be considered in light of various important factors, including, without limitation, the rate of adoption of our CorPath system and the rate of use of our catheters; risks associated with market acceptance, including pricing and reimbursement; our ability to enforce our intellectual property rights; our need for additional funds to support our operations; our ability to manage expenses and cash flow; factors relating to engineering, regulatory, manufacturing, sales and customer service challenges; potential safety and regulatory issues that could slow or suspend our sales; the effect of credit, financial and economic conditions on capital spending by our potential customers; the impact of global and regional economic and credit market conditions on health care spending; health care reform legislation in the United States and its impact on hospital spending, reimbursement and fees which will be levied on certain medical device revenues, decreases in hospital admissions and actions by payers to limit or manage surgical procedure timing and success of product development and market acceptance of developed products; procedure counts; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities, intellectual property positions and litigation, competition in the medical device industry and in the specific markets of surgery in which we operate, the inability to meet demand for products, the results of legal proceedings to which we are or may become a party, product liability and other litigation claims, adverse publicity regarding our company and safety of our products and the adequacy of training; our ability to expand in foreign markets, and other risk factors. Readers are cautioned not to place undue reliance on these forward-looking statements, which are based on current expectation and are subject to risks, uncertainties, and assumptions that are difficult to predict, including those risk factors described in the company’s annual report on form 10-K for the fiscal year ended on December 31, 2016. Our actual results may differ materially and adversely from those expressed in any forward-looking statements. We undertake no obligation to publicly update or release any revisions to these forward-looking statements except as required by law.
**Corindus Today**

A leader in vascular robotics

<table>
<thead>
<tr>
<th>LARGE Market Opportunity with Long GROWTH Runway</th>
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<tbody>
<tr>
<td>$4.5B(^1) market opportunity in 2018 driven by over 2.5 million coronary and 3 million non-coronary procedures performed per year</td>
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<table>
<thead>
<tr>
<th>DIFFERENTIATED Technology</th>
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<tr>
<td>ONLY FDA cleared robotic platform for percutaneous coronary intervention (&quot;PCI&quot;) and peripheral interventions(^2)</td>
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<thead>
<tr>
<th>Proving BENEFIT to Patient, Physician, and Hospital</th>
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<tbody>
<tr>
<td>Robotic precision reduces stent utilization to improve clinical outcomes(^3,4)</td>
</tr>
<tr>
<td>Reducing radiation exposure for patients, physicians &amp; lab staff(^5)</td>
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<tr>
<th>Leading INNOVATION in Vascular Robotics</th>
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<tbody>
<tr>
<td>Strong product development pipeline backed by robust IP portfolio</td>
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<tr>
<td>Open architecture leverages hospital ecosystem &amp; enables partnerships</td>
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1. Market opportunity assessment based on market research reports and Corindus estimate
2. Only the CorPath 200 System is indicated to use in peripheral vascular interventions
Interventional Market Opportunity
Large & growing worldwide market

- $4.5B FY2018 market estimate
- Non-PCI procedure types: Peripheral Vascular, Neurointerventional and Structural Heart
- 2018 estimated PCI procedure volume:
  - 933,000 in the US
  - 1,800,000 OUS
- 2018 estimated non-PCI procedure volume:
  - 1,200,000 in the US
  - 1,800,000 OUS

1. Market opportunity assessment based on market research reports and Corindus estimate
2. Peripheral Vascular includes lower limb, carotid, renal, ICA and AMI (in-hospitalSTEMI) revascularization
3. Millennium Research Group

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$4.5B1
$1.33B NON-PCI
$1.14B PCI
$1.19B NON-PCI
$0.88B PCI
$4.5B

OUS

US

Market Opportunity

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$0.88B PCI
$1.14B PCI
$1.19B NON-PCI
$1.33B NON-PCI
$4.5B1
Company Milestones

- CorPath GRX seeing high utilization in cath labs & 2x increase in adoption with existing customers
  **Adoption**

- Installations at leading centers including Houston Methodist & William Beaumont
  **Commercial Momentum**

- Next Generation
  CorPath GRX cleared by FDA with Guide Catheter Control and Enhanced User Interface

- Global
  Signed Distribution Agreement with 2nd largest company in Japan (Mitsubishi)
Roboticists in the Cath Lab
Second Generation Robotic-assisted PCI System

**CorPath® GRX System**

**BEDSIDE UNIT**
- Optimized bedside unit for radial access
- Simple setup & in-procedure workflow
- Devices fixed during intervention
- Imaging and device agnostic

**INTERVENTIONAL COCKPIT**
- Precise robotic control of
  - Guide catheter
  - Guidewire
  - Balloon/stent catheter
- Radiation-shielded workstation
- 4K resolution monitor enhances visualization of patient anatomy
## Traditional PCI vs Robotic PCI

**Redefining intervention**

### Today's Cath Lab Environment
- High radiation exposure
- Significant fatigue and orthopedic strain

### Manual PCI STEPS
- Struggle to see angiography
- Trial & error, wire spinning
- 'Eyeball' estimate
- Manual adjustment
- Devices loose during inflation

### PCI STEPS
- **Assess Anatomy**
- **Navigate**
- **Measure Anatomy**
- **Position Stent**
- **Deploy Stent**

### Robotic-assisted PCI
- Close proximity ergonomic visualization
- Precise 'Point & Shoot' predictability
- Robotic-assisted sub-mm Measurement
- 1 mm precise positioning
- Fixed devices during deployment

### Robotic Cath Lab
- Shields from radiation
- Potential to reduce fatigue and orthopedic strain
# Why Vascular Robotics

**Benefits for patients, physicians, & hospitals**

<table>
<thead>
<tr>
<th>PATIENT BENEFIT</th>
<th>PROTECTION</th>
<th>FUTURE</th>
<th>DIFFERENTIATION</th>
</tr>
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<tbody>
<tr>
<td>Robotic precision reduces silent utilization by 8.3%¹</td>
<td>95% reduction in radiation exposure to physician²</td>
<td>Significant growth in robotic research and publications</td>
<td>Position hospital on the cutting edge by deploying robotics as part of a hi-tech cardiology model</td>
</tr>
<tr>
<td>17% reduction in radiation exposure to patient²</td>
<td>Sit comfortably without the need for lead</td>
<td>Relevancy</td>
<td>Clinical leadership</td>
</tr>
<tr>
<td>May facilitate increased radial adoption, which is shown to improve clinical outcomes</td>
<td>15% reduction in radiation exposure to bedside staff³</td>
<td>Involvement in tech development and medical education</td>
<td>Attract &amp; retain physicians</td>
</tr>
</tbody>
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Evolution of Interventional Treatment
Hi-tech cardiology model with robotics

- **Current Robotic Capabilities**
  - Precise Treatment
    - Precise robotic movement
    - Enhanced visualization
    - Multi-device control
  - Safety & Wellness
    - Physician safety & comfort
    - Staff safety & skill development
    - Patient safety
  - Differentiation
    - Enable radial adoption
    - Robotic program marketing

- **Future Robotic Capabilities**
  - Improved Capabilities
    - Lesion assessment
    - Lesion preparation
    - Expanded device compatibility
  - Access to Care
    - Teleproctoring
    - Telesenting
  - Improved Efficiency
    - Integrated decision making tools
    - Procedural automation
    - Prescriptive analytics

- **Traditional PCI**
  - Clinical Outcomes
    - Good success rates
    - Increasingly complex cases
  - Occupational Hazards
    - High risk working environment
    - Physician burnout
  - Stagnant Market
    - Competition for market share
    - Radial adoption slow
Vascular Robotic Clinical Roadmap

Demonstrating excellence in multiple lesion types and anatomies

- Expand Use
- Feasibility
- Exploratory

Robotic system capability

- PCI
- PERIPHERAL
- NEURO

- Expand Use
- Feasibility
- Exploratory

PCI
- Below the Knee
- Ostial Stenting
- Atherectomy
- Drug Eluting Balloons

CorPath 200 and CorPath GTP Systems are indicated for PCI. Only the CorPath 200 System is indicated for use in peripheral vascular interventions.
CorPath Systems are not indicated for use in neuro or structural interventions.
Catalysts & Strategic Objectives

FOUNDATION: THREE PILLARS OF GROWTH

- Technology Development
- Market Expansion
- Global Adoption

Expanding Indications Peripheral
Software Enhancements 1st Automated Movement
Japan Commercial Launch
Expanding Capabilities Additional Automated Movements
China Planned Expansion
Remote Capabilities Telemonitoring
Expanding Indications Neuro/Stroke

2016 2019-2020 2021-2023
About Corindus Vascular Robotics

Corindus Vascular Robotics, Inc. is a global technology leader in robotic-assisted vascular interventions. The company’s CorPath® System is the first FDA-cleared medical device to bring robotic-assisted precision to percutaneous coronary interventions. With the CorPath System, Corindus Vascular Robotics brings robotic precision to interventional procedures to help optimize clinical outcomes and minimize the costs associated with complications of improper stent placement with manual procedures.

Visit us at www.corindus.com