

ENDOCYTE INC
Form DFAN14A
October 18, 2018

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

SCHEDULE 14A

(Rule 14a-101)

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

**Proxy Statement Pursuant to Section 14(a) of
the Securities Exchange Act of 1934 (Amendment No.)**

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Endocyte, Inc.

(Name of Registrant as Specified In Its Charter)

Novartis AG

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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This communication contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995, that can generally be identified by words such as to acquire, to transform, candidate, potential, expected, offers, to accelerate, ongoing, would, potentially, believe, can, hopefully, excited, pipeline, ambition, priorities, to strengthen, opportunity, subject to, planned, or similar expressions, or by express or implied discussions regarding the proposed acquisition of Endocyte by Novartis including the potential outcome and expected timing for completion of the proposed acquisition, and the potential impact on Novartis of the proposed acquisition, including express or implied discussions regarding potential future sales or earnings of Novartis, and any potential strategic benefits, synergies or opportunities expected as a result of the proposed acquisition; and regarding potential marketing approvals, new indications or labeling for the potential and investigational products described in this communication and the potential timing of any such approvals, or regarding potential future revenues from any such products. You should not place undue reliance on these statements. There can be no guarantee that the acquisition described in this communication will be completed, or that it will be completed as currently proposed, or at any particular time. There can be no guarantee that Novartis or any potential products that would be obtained with Endocyte will achieve any particular future financial results, or that Novartis will be able to realize any potential strategic benefits or opportunities as a result of the proposed acquisition. There can be no guarantee that the potential and investigational products described in this communication will be submitted or approved for sale in any market or at any particular time. There can be no guarantee that such products will be commercially successful in the future. In particular, our expectations could be affected by, among other things: regulatory actions or delays or government regulation generally, including potential regulatory actions or delays relating to the completion of the potential acquisition described in this release, as well as potential regulatory actions or delays with respect to the development of the products described in this release; the ability to obtain Endocyte stockholder approval and the satisfaction of the other conditions to the consummation of the proposed acquisition; the potential that the strategic benefits or opportunities expected to result from the proposed acquisition may not be realized or may take longer to realize than expected; the potential that the integration of Endocyte into Novartis subsequent to the closing of the proposed acquisition may not be successful, or may take longer to succeed than expected; potential adverse reactions to the proposed acquisition by customers, suppliers or strategic partners; dependence on key Endocyte personnel, customers and suppliers; the uncertainties inherent in the research and development of new healthcare products, including clinical trial results and additional analysis of existing clinical data; our ability to obtain or maintain proprietary intellectual property protection; safety, quality or manufacturing issues; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures; the particular prescribing preferences of physicians and patients; uncertainties regarding actual or potential legal proceedings, including, among others, potential legal proceedings with respect to the proposed acquisition; and other risks and factors referred to in Novartis AG's filings with the U.S. Securities and Exchange Commission, including the Forward-Looking Statements and Risk Factors sections of Novartis AG's current Form 20-F for the fiscal year ended December 31, 2017. Forward-looking statements are based on information, plans, estimates, beliefs and expectations regarding future events as of the date they are made and are subject to significant known and unknown risks and uncertainties, and there may be other factors that may cause actual results to differ materially from these forward-looking statements. Novartis undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, subsequent events or otherwise, except as required by applicable law.

Additional Information and Where to Find It

This communication may be deemed to be solicitation material in respect of the proposed acquisition of Endocyte by Novartis AG. In connection with the proposed acquisition, Endocyte intends to file relevant materials with the SEC, including a proxy statement in preliminary and definitive form. **Stockholders of**

Endocyte are urged to read these materials (including any amendments or supplements thereto) and all other relevant documents filed with the SEC when such documents become available, including Endocyte's definitive proxy statement, because they will contain important information about the proposed acquisition. Investors and security holders are able to obtain the documents (once available) free of charge at the SEC's web site, <http://www.sec.gov>, or from Endocyte by going to its investor relations web site at <http://investor.endocyte.com/investor-relations>

Participants in Solicitation

Novartis AG and its directors and executive officers, and Endocyte and its directors and executive officers, may be deemed to be participants in the solicitation of proxies from the holders of Endocyte shares of common stock in respect of the proposed acquisition. Information about the directors and executive officers of Novartis AG is set forth in the excerpts of Novartis AG's Annual Report for 2017, which was furnished to the SEC on Form 6-K on January 24, 2018 and incorporated by reference into Novartis AG's Annual Report on Form 20-F for the fiscal year ended December 31, 2017. Information about the directors and executive officers of Endocyte is set forth in the proxy statement for Endocyte's 2018 Annual Meeting of Stockholders, which was filed with the SEC on March 23, 2018. Information regarding interests of Novartis AG's and Endocyte's respective participants in the solicitation, will be set forth in the proxy statement relating to the proposed acquisition and other materials to be filed with the SEC in connection with the proposed acquisition.

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On October 18, 2018, Novartis AG (*Novartis*) hosted a conference call and webcast in connection with its third quarter 2018 results and its proposed acquisition (the *Proposed Acquisition*) of Endocyte, Inc. (*Endocyte*). Set forth below are excerpts from the transcript of such conference call and webcast relating to the Proposed Acquisition.

Samir Shah - Novartis AG - Global Head of IR

Thank you very much, and good morning, and good afternoon, everybody.

Before we start, I just wanted to read to you the safe harbor statements. The information presented today contains forward-looking statements and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. Please refer to the company's Form 20-F on file with the U.S. Securities and Exchange Commission for a description of some of these factors.

In addition, I just wanted to point out that the information presented in respect to the proposed Endocyte transaction may be deemed to be solicitation material. In connection with the proposed Endocyte transaction, Novartis and Endocyte intend to file relevant materials with the U.S. SEC. We urge you to read these materials, including a proxy statement of Endocyte and all other relevant documents filed with the SEC when such documents become available and which will be available for free. The proposed Endocyte transaction has not been completed, and there can be no guarantee that the proposed Endocyte transaction will be completed or that it will be completed as currently proposed or at any particular time.

And with that, I'll now hand the call to Vas.

Vasant Narasimhan - Novartis AG - CEO

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

We're also quite pleased with our innovation milestones in the quarter, and I'll go through these in the upfront section, but with the AVXS-101 filing in U.S., Europe and Japan, BAF312 filed in U.S. and Europe, the approval of Kymriah in multiple geographies and the proposed acquisition of Endocyte, I think we're also demonstrating we have the innovation power and the innovation momentum to continue to drive growth well into the future.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

I mentioned Lutathera, and I wanted to show on Slide 9 the kind of really explosive performance we're seeing now in Lutathera. It's off to a strong start in the U.S. You can see here number of doses per quarter, and this trend is really I think really encouraging. Now we're starting to roll out the medicine in Europe. In the U.S., we have 85 centers that are actively prescribing. We have 70% coverage of the relevant lives. And in the U.K. now, we have 18 centers actively prescribing. And I think, seeing the strength of the performance in Lutathera, feeling now that it's a

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potential blockbuster medicine, seeing this outperform is part of the rationale when we come to the Endocyte deal for the confidence we had in taking the step to acquire Endocyte. And I'll talk more about that in a few slides.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

When you go to Slide 12, just to say a word within the quarter, we had a number of key data readouts and regulatory milestones. And I don't want to go through all of this, but I feel I wanted to highlight on this slide. I will talk about AVX-101 and Endocyte specifically, but I did want to note that BAF312 was filed in in both U.S. and Europe.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Going to Slide 16. I want to say a word now about few slides about Endocyte, the acquisition we announced earlier today, which really builds on the earlier acquisition we've made with Advanced Accelerator Applications. As I've tried to articulate to all of you, we're on a journey to focus our company as a medicines company. And within being a medicines company, along with our appropriate diversification and therapeutic area to build leadership in 3 platforms, which we believe are advanced therapy platforms that will drive differential growth. Cell therapy, we have Kymriah and then building beyond that, gene therapy, we've acquired AveXis and building on our portfolio there. And finally, in radiopharmaceuticals or radioligand therapy in this case.

Now when you look at the specific assets we have here in Endocyte, which we would plan to bring into our Advanced Accelerator operation, prostate cancer is expected to be an \$11 billion market globally in 2024. This medicine is expected to provide an additional treatment option for prostate cancer. And I'll talk more about that because I think there is some misunderstanding in some of the notes I've seen over the course of today as to what exactly we're treating here versus other therapies that are on the market. And this is the first-to-market potential product in our PSMA radioligand therapy. The enrollment of Phase III has been initiated and is on track. FDA feedback, which we reviewed is very clear that radiographic BFF can be used as the endpoint, which should enable a relatively rapid, we believe, timeline for the Phase III study.

It's a significantly derisked profile when you look at the paper that's been published on the strong Phase II data. There's extensive preclinical data as well as various other investigator-initiated data that we've reviewed, which gives us confidence in the overall profile of the medicine.

Now importantly, this expands our nuclear medicine platform following the launch of Lutathera, given the second radioligand therapy. It allows us to eventually move this PSMA 617 therapy into earlier lines of therapy. And then we have opportunities to expand the platform in the future. One thing not noted in the slide is also would enable us to have a new manufacturing capabilities that we could then apply to our radioligand portfolio in the future.

So when you go to Slide 17, what exactly do we talk about here. And this is, I think, a very important point, and I hope investors will take a moment. This is a therapy, as is the case with Lutathera, where we link a radioactive particle to a ligand. And this ligand has high specificity for a given tumor cell type. And that way, we can target the radiation directly to the relevant cancer. So it's a very targeted approach. We do that with neuroendocrine tumors. And here, we do it with PSMA and prostate cancer. The high-affinity targeting allows us to really manage. I think improve the efficacy and also manage the safety profile.

Now other therapies available in the market are simply infusions of radium that are actually just used for bone metastases, not for metastatic prostate cancer. So if you look at your benchmarks for what are the appropriate sales potential, please ensure you are using relevant benchmarks when you do this. Now once this is bound the particles are bound together, they get internalized, then you would expect that the cancers then ultimately respond. And that's a response that we've seen. And when you look at the data on Slide 18, you can see here in the Phase II study, we had a strong PSA response, which we think is a relative measure. You can see on the left-hand side. We had a solid trend in these patients, who have failed multiple lines of therapy in PFS, as well as an overall survival. And we've seen similar data from other smaller studies sets and ISPs as well.

So when you go to the next slide, you can see our the Phase III VISION trial, which is currently enrolling,

take the 2-to-1 randomization, take patients with metastatic prostate cancer, they have to have a positive PSMA scan and then have had a priority taxane or a prior novel androgen access drug. And after that, then they're randomized into either the PSMA drug or the best supportive care, then we see. We have 750 patients enrolled and initiated. And as I said, FDA has agreed to the endpoints on both primary and secondary.

So when you go to Slide 20, you can see that some of the deals and some of the deal characteristics. We're certainly happy to answer any questions, but I think it's relatively straightforward. We fund it through Cash. We don't expect dilution with respect to this deal. We expect it to start contributing to group sales in 2021. Our overall financial expectations if the medicine has a blockbuster potential, and if we're able to get into earlier lines of therapy, we can have even higher sales potential with this medicine, which would generate an attractive IRR to the company. And of course, all of this is subject to the appropriate approvals from Endocyte shareholders and the relevant regulatory agencies.

So if you go to Slide 21, expected next steps for the deal. Of course, we'll continue to generate the data and provide additional information as it becomes available. We have filed a proxy statement we will file the proxy statement with the SEC, and we are hopeful to have closing in the first half of 2019, subject to the various considerations.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Vasant Narasimhan - Novartis AG - CEO

We progressed our advanced therapy platform strategy with the agreement to acquire Endocyte, and we are on track to deliver our full year guidance.

So with that, we can open up the line for questions.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Matthew Weston - Crédit Suisse AG, Research Division - MD and Co-Head of European Pharmaceutical Equity Research

And then finally, Vas, on Endocyte. The one thing that surprised us, the deal structure as a merger rather than a tender, which often suggests that there are competition concerns. Whether or not you're prepared to comment or whether or not you expect competition commission scrutiny or whether it's not around that CAR-T platform or whether it's around the Lutetium platform and how you see that playing out?

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Vasant Narasimhan - *Novartis AG - CEO*

And then lastly with respect to Endocyte and the structure of the deal, Harry?

Harry Kirsch - *Novartis AG - CFO*

Thank you, Matthew. So there are no specific concerns here. Just the structure that both parties agreed upon to do a one-step merger versus a tender offer. So nothing specifically to read into that.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Richard Vossler - *JP Morgan Chase & Co, Research Division - Senior Analyst*

Richard Vosser, J.P. Morgan. Just a question on the Endocyte deal, first of all. Just first of all, can you give us some help in terms of the proportion of prostate cancer patients express their PSMA operating on them? And also, thinking about the initial indication that you're doing in Phase III trial, it looks like it might be post taxane. So does that mean you have to fail tax first? Just some thoughts on the positioning there. And perhaps you can give us an idea of whether the royalty payments still stand to AVX post the transaction, whether those stand. And also on the manufacturing, you talked about that being important. Perhaps, you could update us and think about the capacity that it brings along with that.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Vasant Narasimhan - Novartis AG - CEO

Great. Thank you, Richard. So first question on just the overall landscape for prostate cancer PSMA. Liz?

Elizabeth Barrett - Novartis AG - CEO of Novartis Oncology

Sure. There's about 70% to 80% of patients express PSMA. To and answer your question directly, yes, in the trial we've shown, you do have to fail at least 1 taxane. Doesn't have to be taxotere, but it has to be 1 taxane. Our goal is in the future to move it earlier in the treatment paradigm, so we will we will begin to think about that post close. And as far as commenting as far as the royalty is concerned at this point. And then lastly, around the manufacturing, there's different types of manufacturers. There's direct and indirect, and the message that they have is really just give us the capability of being able to generate less waste and have a more purified therapy. So we're looking at how we leverage technology and expertise over to AAA. And I think, from that perspective, that sort of answers that question of what we think is the benefit of the manufacturing. They are currently using a CRO, so I think our ability post close to look at the total manufacturing and see the best way forward, we'll look at that post close.

Vasant Narasimhan - Novartis AG - CEO

And it's certainly our aspiration to drive that synergy the capability we have within AAA to reach patients eventually all around the world through our supply chain.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Unidentified Analyst

Also, a couple of questions on the Endocyte deal. The first, in terms of the positioning. I understand it's going to be much broader than the Pharmaceuticals going into prostate cancer. But ultimately, in that space, is my understanding correct that you will still be competing because you wouldn't be giving 2 radiopharmaceuticals, one treating just the bone and one treating effectively that plus something else? And then the second question on that is also, I mean given the somewhat checkered history of radiopharmaceuticals in prostate cancer, would you say that you don't expect any similar problems for your product because it's not Endocyte product because it's much more targeted? Or are there any particular learnings for your own clinical programs, in particular, settings or patient segments that you want to go after?

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]

Elizabeth Barrett - *Novartis AG - CEO of Novartis Oncology*

Moving to the prostate and to Endocyte, I think there's again a little bit of a misunderstanding. This

therapy is for all patients to treat prostate cancer. I think that's the most clear way that I can explain it. It's not to treat a side effect or any other part of prostate cancer is to treat prostate cancer. And what's happening in prostate cancer, I think it's really important to think about the evolution of what's happened in prostate cancer, the antiandrogen therapy, particularly the novel antiandrogen therapies, are moving into the non-metastatic settings. So you're seeing the need for more therapies in the metastatic setting. And so we see that this will be an important medicine for all prostate patients with PSMA, that I noted before, it's about 70% to 80% of the patient population. I think we demonstrated with through the launch of Lutathera, that we can bring this important therapy to patients, and that physicians and centers and nuclear medicine physicians are interested in and excited about bringing these types of therapies to patients. So I think we felt very good about the prospects for the prostate cancer area. It's a large market, and these patients are in need of additional therapy.

Unidentified Analyst

Can I just sorry can I just clarify on that point because I thought that the vast majority of metastatic patients (inaudible) develop main metastases are at the bone met. So are you basically expecting to be as good on bone met as other therapies, but have the broader application? Or (inaudible) separately

Vasant Narasimhan - Novartis AG - CEO

Let me try one more time, Maria. When you think about radiopharmaceuticals traditionally conceived, you're infusing a radioactive compound systemically IV. And those radioactive compounds have certain affinities. So radium has affinity in places where there is calcium. So radium builds up in the bone. So you have systemic side effects. And if you don't have a very targeted approach to all of where you find the relevant cancer because this is really infusing a radioactive agent. Radioligand therapy, which is what we do with Advanced Accelerator Applications and what we do here with Endocyte, links a scientifically well-understood ligand that's specific to a specific cancer that links to a radioactive particle through conjugation chemistry. In the case of prostate cancer, there is a well-understood androgen called prostate-specific membrane antigen, PSMA, which is used as a diagnostic and ultimately used for treating the cancer. So our aspiration is, based on all the science we understand, is that these PSMA are overexpressed prostate cancer cell. So wherever you find prostate cancer in the body, you will be able to treat with radioligand therapy as that by Endocyte. Our expectation is we will be able to work well in bone met, but more importantly, we will work well for anywhere in the body that you find prostate cancer. And then we hope to create overall survival benefit and progression-free survival benefits in the indication of prostate cancer.

[Portions of the transcript that are unrelated to the Proposed Acquisition are omitted.]
