Increasing Precision in Prostate Cancer, a FOCAL Point ONE Should Not Ignore; Initiating at Buy, $5.50 PT

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STOCK DATA	
Market Cap (mil)	$65.5
52-Week Range	$1.46 – $5.40
3-Month ADTV	121,795
Shares Outstanding (mil)	29.0
Float (%)	99.6
Short Interest	37,465
Fiscal Year-End	December

EARNINGS DATA			
EPS	2019A	2020E	2021E
1Q	€0.01	€(0.03)	—
2Q	€0.05	€(0.05)	—
3Q	€0.00	€(0.07)	—
4Q	€(0.01)	€0.00	—
FY	€0.05	€(0.16)	€0.02
P/E	42.5x	NM	NM

FINANCIAL DATA			
FY	2019A	2020E	2021E
Total Revenue	44.9	31.1	44.4

Total Revenue: In €millions.

BALANCE SHEET DATA	
	4Q19
Cash & Equivalents	€20.9
Current Assets	€42.1
Total Liabilities	€17.5
Shareholders' Equity	€27.4

ADS price, price target, market cap, and enterprise value are in USD. Financials are EUR. All data is in millions, expect per share data.

Summary and Recommendation

We are initiating coverage of EDAP TMS SA (EDAP) with a Buy rating and a 12-month PT of $5.50 per ADS. EDAP is a leading provider of robotic energy-based urology therapy systems. The company operates through two core platforms/divisions, Urology and Devices Services (UDS) and High Intensity Focused Ultrasound (HIFU), which are primarily used in the treatment of urinary stones and localized prostate cancer (PCa), respectively. EDAP's offerings are sold in over 50 countries and have been demonstrating strong growth and margin expansion, which we believe are poised to increase due to Focal One—EDAP's latest HIFU offering, which has industry-leading focal ablation abilities—new indications and product launches, and expected reimbursement tailwinds. We believe Focal One provides significant benefits relative to other treatment options for localized PCa patients, filling a meaningful and growing white space in today's treatment paradigm. While we expect COVID-19 to be a headwind, we believe its impact is reflected in the current share price and believe market dynamics favor Focal One and EDAP's broader portfolio, which position its operations to rebound on the other side of COVID-19. Moreover, we believe EDAP's current operations more than support its current valuation, as EDAP trades over 2 turns below the ~3.5x EV/S multiple of our comp group, which we believe provides a meaningful opportunity.

Key Points

- **Focal One offers a significant and underappreciated opportunity.** We believe that Focal One is EDAP's largest growth opportunity. It provides physicians and patients with a noninvasive, more precise treatment option for PCa relative to previous HIFU platforms and other treatment options in the market. Furthermore, the offering fills a significant void in the current treatment paradigm, the white space between active surveillance (i.e., no therapy) and radical surgery/radiation therapy. While Focal One is new to the market, particularly domestically, it has been showing significant growth as a treatment option. Although Focal One's current domestic reimbursement often burdens patients with a significant portion of the out-of-pocket costs for the procedure, we believe that this is set to be resolved in 2021, likely favorably positioning the system for increased adoption and accelerated growth.
- **Numerous incremental growth levers.** Atop its positioning in PCa, we believe that Focal One has potential in numerous other indications, and EDAP is running clinical trials to expand into rectal endometriosis, liver cancer, pancreatic cancer, and as a treatment for placenta accreta. We believe these additional indications are more than double EDAP's opportunity in PCa. Moreover, EDAP's UDS business has shown a consistent cadence. We expect this to continue, as the company's latest offering, Endo-UP, its first integrated, end-to-end urinary stone platform, is expected to hit the market in the coming quarters.
- **Metrics highlight inflection point.** In 2019, EDAP grew its top line by 15% to €44.9M, led by higher-margin HIFU sales increasing 28% Y/Y, and flipped profitable for the year. We believe that EDAP will continue to show strong growth in a normalized environment and that the receipt of a CPT code and the Endo-UP launch should further benefit the company. However, we are modeling a meaningful impact to its business through 3Q20 due to COVID-19. As a result, we are modeling EDAP's top line/adjusted EPS going from €44.9M/€0.05 in 2019 to €31.1M/€(0.16), €44.4M/€0.02, and €55.8M/€0.11 in 2020–2022, respectively.
- **Initiating at Buy, $5.50 PT.** We believe EDAP's unique robotic energy-based therapies, favorable clinical data, and growth potential strongly position the company over the coming years. We base our $5.50 PT on a 3x EV/sales multiple against our 2021 revenue estimate of €44.4M. We adjust our projections from EUR to USD at current exchange rates to obtain our per-ADS price target. (EDAP reports its financials in EURs, but ADSs trade in USDs).

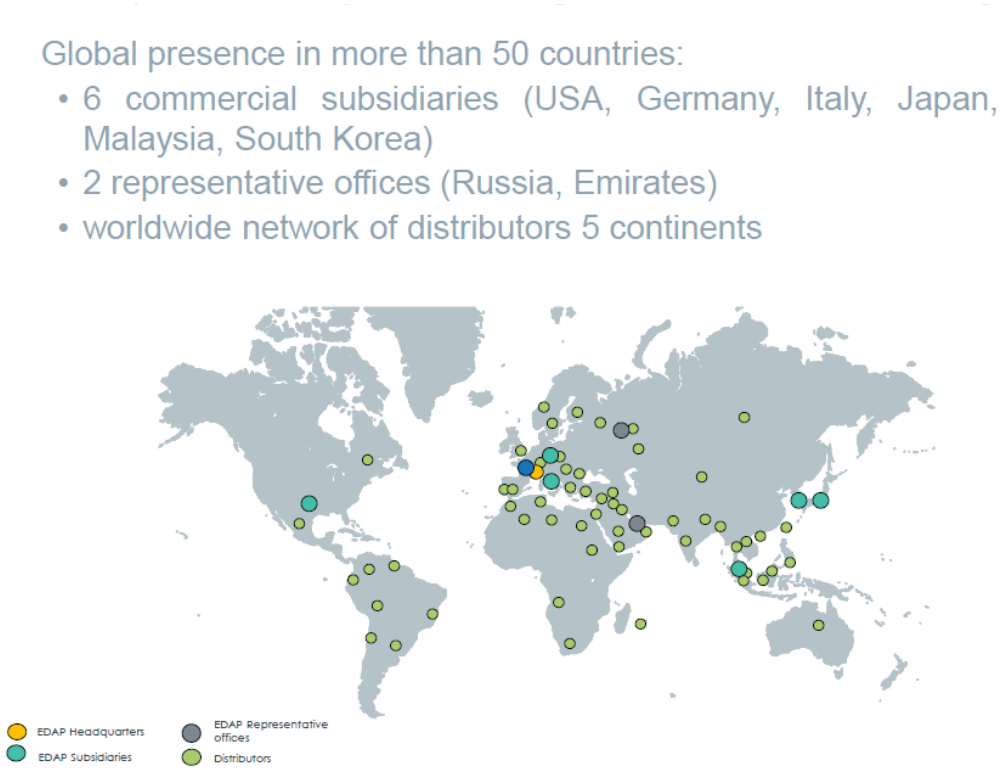
Company Overview

EDAP is a commercial-stage medical technology company that is headquartered in Lyon, France, with subsidiaries and/or facilities in Texas, Malaysia, Italy, Germany, Japan, South Korea, Russia, and United Arab Emirates. The company is a leading provider of minimally invasive medical devices that primarily deliver robotic energy-based therapies for urological diseases in over 50 countries (see Exhibit 1). EDAP's proprietary HIFU and extracorporeal shockwave lithotripsy (ESWL) systems are currently utilized for precision soft tissue ablation for localized PCa and for the treatment of urinary stones (e.g., kidney stones, gallstones), respectively.

EDAP was founded in 1979 and was initially focused on manufacturing and distributing ultrasound scanners and, in 1985, developed the first piezo-electric lithotripter, a second-generation ESWL platform. Through liquidation, in 1994, EDAP acquired the majority of the assets from Technomed International S.A., through which it obtained additional lithotripter technologies and expanded its presence in urologic conditions by acquiring its HIFU platform, as well as a transurethral microwave thermotherapy (TUMT) platform for the minimally invasive treatment of benign prostatic hyperplasia (BPH). After which, EDAP began developing HIFU as a treatment for prostate cancer and launched next-generation systems and new offerings for its other target indications. In 1999, EDAP obtained CE Mark approval for its first-generation HIFU system, Ablatherm Maxis, and subsequently sold its TUMT platform in 2000. Since then, EDAP has continued to advance and introduce new generations of its HIFU and ESWL platforms. The company obtained CE Mark approval for Focal One in 2013, and in 2015, 2017, and 2018, it obtained 510(k) clearance from the FDA for its Ablatherm Integrated Imaging, Ablatherm Fusion, and Focal One HIFU systems, respectively. EDAP went public through an IPO in 1997, and its ADS units are listed on the NASDAQ under the ticker "EDAP."

Today, EDAP is working to gain market share for its various systems in existing markets through an internal sales force, as well as through international strategic partnerships and distribution agreements. In addition to increasing its market penetration, EDAP is focused on continuously expanding its market opportunity by introducing new platforms and increasing the number of indications that its core technologies can treat. The company currently generates revenue through four avenues: (1) the direct sale of its various systems and, in some regions, third-party equipment/systems through distribution agreements; (2) indirect sales through its distribution partnerships; (3) spare parts and service revenues, which are received through maintenance contracts with installed systems; and (4) the sale of disposables, primarily Ablapaks and Focalpaks for its HIFU division and electrodes for its UDS division.

Exhibit 1: EDAP's Offices and Global Distribution Network



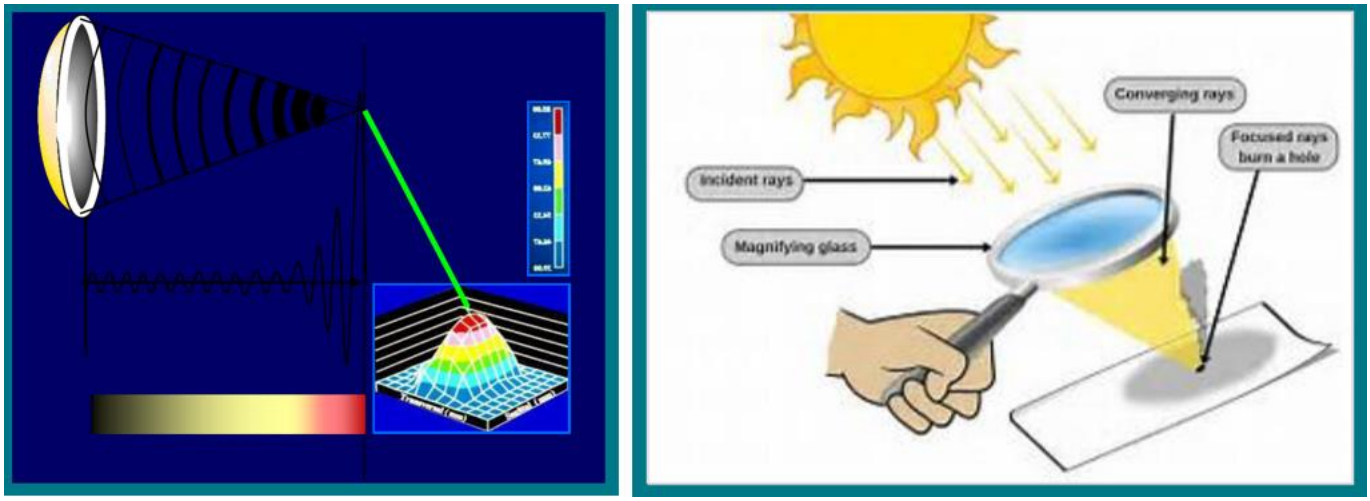
Source: Company reports

Business Overview

The backbone of EDAP's business is its proprietary ultrasound technology and expertise that has been integrated into its HIFU and ESWL platforms, which are the core technology sets for the company's HIFU and UDS divisions, respectively. We believe the largest growth opportunity for EDAP exits within its HIFU division, primarily related to revenue streams generated through EDAP's Ablatherm and Focal One systems. The division posted 28% Y/Y growth in 2019 and accounted for ~31% of EDAP's sales of €44.9M, up from 28% of 2018's consolidated sales of €39.2M.

HIFU is capable of destroying soft tissue in a small target zone while preserving tissue outside of its target area. HIFU uses a transducer to create a convergent, high-intensity ultrasound beam to heat tissue to over 85°C at the focal point. Alternating positive and negative energy is absorbed to targeted cells to rapidly heat tissue and cause coagulative necrosis. HIFU essentially works similarly to how light is focused under a magnifying glass to super-heat a point. HIFU's ability to target a focal point enables surgeons to ablate tissue that might be multiple layers below the surface, eliminating the need for incisions while still enabling the destruction of diseased tissue without damaging surrounding tissue and organs.

Exhibit 2: HIFU Schematic



Source: Company reports

Ablatherm and Focal One are EDAP's two HIFU platforms. Ablatherm is the company's original HIFU platform; this first-generation system was the first commercial HIFU to enter the market, obtaining CE Mark clearance in 1999. Since then, EDAP has introduced several Ablatherm systems, with its second and third iterations, Ablatherm Integrated Imaging and Ablatherm Fusion, being its first HIFU systems to receive FDA clearance in 2015 and 2017, respectively. Meanwhile, EDAP's Focal One platform obtained CE Marking in 2013 and FDA 510(k) clearance in 2018.

EDAP currently markets three HIFU systems: Ablatherm Integrated Imaging, Ablatherm Fusion, and Focal One. Ablatherm systems are utilized to treat T-1 and T-2 (based on the TNM [primary tumor, regional lymph nodes, distant metastasis] rating scale, see Exhibit 3) PCa, which are typically considered to be low- or intermediate-risk types of PCa, where malignancy is localized (organ confined) to the prostate gland. While Focal One is also used to treat T1–T2 stage PCa, it has the potential to provide lesion-specific focal therapy, enabling it to destroy targeted cancer cells, rather than being used for a hemi-ablation or whole-gland ablation, which account for the majority of HIFU treatments to date. Moreover, all the devices can be used as a salvage therapy in instances where PCa relapses after radiation therapy.

All three devices have received 510(k) clearance by the FDA and are indicated for the ablation of prostate tissue, and the Ablatherm Integrated Imaging and Focal One are CE marked/indicated in Europe and other regions for the treatment of localized PCa. We expect Focal One to account for the majority of EDAP's HIFU system sales going forward.

Exhibit 3: TNM Staging

Classification		Definition
Tumor (T)		
T0		No evidence of primary tumor
T1	T1	Tumor is not visible
	T1a	Tumor is <=5% of the prostate
	T1b	Tumor is >5% of the prostate
	T1c	Tumor is diagnosed on needle biopsy only
T2	T2	Tumor is confined to the prostate
	T2a	Tumor is confined to one-half of one lobe or less
	T2b	Tumor is confined to >one-half of one lobe but not both lobes
	T2c	Tumor has spread to both lobes
T3	T3	Tumor extends through the prostatic capsule
	T3a	Extracapsular extension is present
	T3b	Tumor has spread to the eminal vesicles
T4		Tumor has spread to adjacent structures: bladder neck, external sphincter, rectum, levator muscles, pelvic wall
Regional lymph nodes (N)		
N1		PCa has spread to regional lymph node(s)
Distant metastases (M)		
M1	M1	Cancer has spread beyond the prostate
	M1a	PCa has spread to non-regional lymph node(s)
	M1b	PCa has spread to the bone(s)
	M1c	PCa has spread to other sites/organs (doesn't need to include bone)

Source: National Cancer Institute and B. Riley FBR, Inc.

Exhibit 4: EDAP HIFU Regulatory Approvals

System	CE Mark	510(k)
Ablatherm Maxis	1999 Approved for local treatment of prostate cancer	
Ablatherm Integrated Imaging	2005 Approved for local treatment of prostate cancer	2015 Approved for prostate tissue ablation
Ablatherm Fusion		2017 Approved for prostate tissue ablation
Focal One	2013 Approved for local treatment of prostate cancer	2018 Approved for prostate tissue ablation

*Ablatherm and Focal One can also be utilized as treatment where PCa relapses after radiation therapy.

Source: Company reports and B. Riley FBR Research

Ablatherm Integrated Imaging is a mobile transrectal ultrasound guided robotic HIFU system that enables physicians to visualize and define the treatment area within the prostate and control the procedure in real time. The system's platform automatically calculates the treatment distribution of lesions and automatically operates the HIFU beams at predefined areas until the treatment is completed. Ablatherm Fusion builds upon Ablatherm Integrated Imaging by incorporating EDAP's proprietary fusion software, which merges MRI/multi-parametric magnetic resonance imaging (mpMRI) and/or targeted biopsies to the system's real-time ultrasound images, providing physicians with a much more granular visualization of lesions within the prostate, therefore, helping to substantially increase accuracy during planning and treatment. Both Ablatherm systems' ablation treatment zones have a width of 1.7 mm, and the depth can range from 19 mm to 24 mm.

Focal One is EDAP's most advanced HIFU system. The most notable difference between the system and Ablatherm Fusion is that Focal One (1) uses a proprietary dynamic focusing technology that allows a precise, non-invasive destruction of the target area within the prostate, which also enables the electronic displacement of the focal point without any mechanical movement; (2) has an increased treatment depth range (5 mm–40 mm versus 19 mm–24 mm), which allows it to treat larger/enlarged prostates or smaller points within the prostate; and (3) is not a mobile system (see Exhibit 5).

As a result, Focal One is the first HIFU system to enable precise focal ablation with limited margins around lesions, versus hemi-ablation or with larger lesion-specific margins. Focal One is primarily being targeted toward larger hospitals and academic institutions, unlike the Ablatherm systems, which are currently being used more frequently at smaller institutions, ambulatory surgery centers (ASCs), and private practices; however, we expect Focal One to likely be utilized across institutions of all sizes and expect EDAP to make a significant push into that market in 12 to 24 months, likely after more leading centers adopt the system and assuming headwinds related to the COVID-19 pandemic are able to be mitigated. Meanwhile, Focal One has a ~$695k list price, versus Ablatherm Fusion at ~$320k.

Exhibit 5: Select Differences between EDAP's Ablatherm Fusion and Focal One Systems

Product Offering & Positionning

CE FDA	ABLATHERM FUSION *HIFU For Prostate Tissue Ablation*	FOCAL ONE *Premium Device for Focal Therapy in Prostate Ablation*
Diagnostic Information	Ultrasound + MRI Imaging	Ultrasound + MRI Imaging
Dynamic Focusing		✓
Mobile Unit	✓	
Targeted Customer	ASC & Small-Medium Hospitals	Large academic institutions
Price Point	$320K	$695K

Source: Company reports

Currently, patients that are diagnosed with localized PCa are primarily treated with radical prostatectomy (RP), with radiation therapy (RT)—which includes external beam treatments, such as intensity modulated radiotherapy (IMRT) and stereotactic body radiotherapy (SBRT), as well as brachytherapy—or through active surveillance (AS). AS involves routine follow-up PSA screening, rectal exams, and potentially mpMRI. EDAP estimates that ~35% of patients undergo RP, ~45% are treated with RT, and ~20%–25% undergo AS.

It is important to note that there are significant drawbacks to each treatment option. There is a growing amount of literature noting that, while effective, RP can be an overtreatment for a significant percent of patients with localized, low-risk PCa. Mortality rates due to localized low-risk PCa are low, and RP has "significant morbidity: impotence (> 50%), ejaculatory dysfunction (100%), orgasmic dysfunction (50%), incontinence (< 5%–30%), pulmonary embolism (< 1%), rectal injury (< 1%), urethral stricture (< 5%), and transfusion (20%)."

RT, in many instances, is also considered to be an aggressive treatment option for localized PCa, particularly for low- to intermediate-risk forms, and typically results in off-target radiation exposure. Furthermore, the chances of side effects (e.g., urinary incontinence and erectile dysfunction) are increased when other treatment options are subsequently performed. This can impact a meaningful percentage of patients that have undergone radiation therapy, as the treatment has been shown to have an ~40% failure rate and is typically not recommended for repeated use.

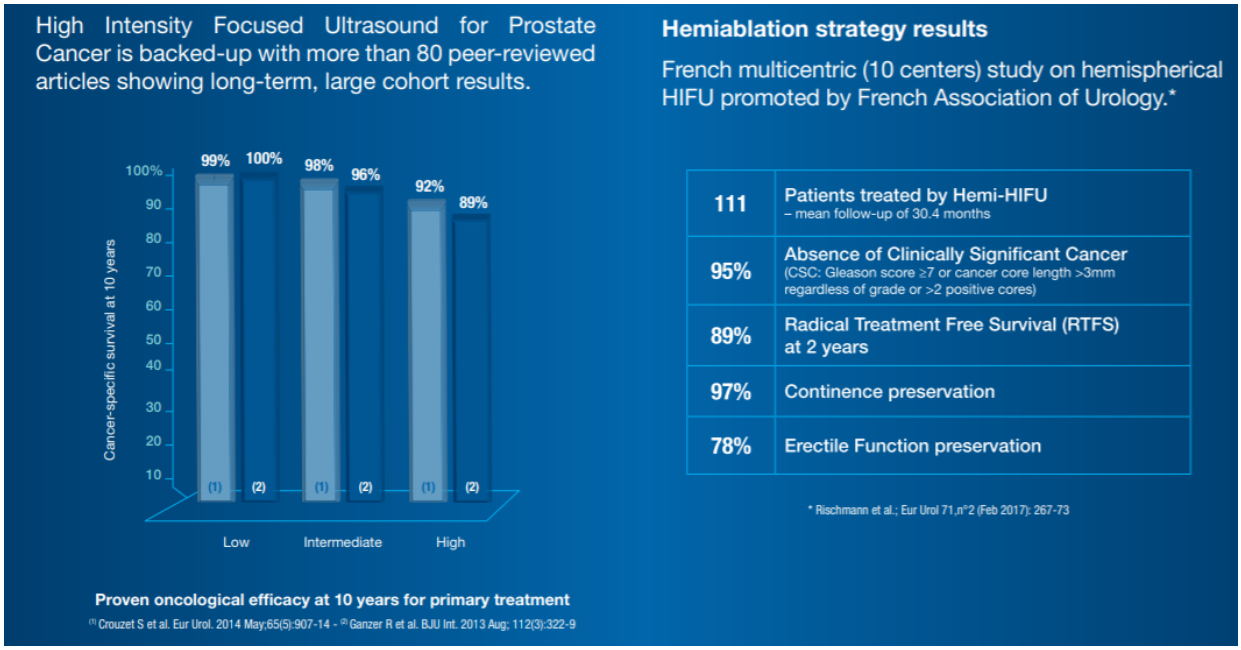
In contrast to RP, HIFU's side effects can be far less pronounced. For example, data from a 111-patient prospective study initiated by the French Urological Association and published in *European Urology* in 2016 showed promising results for hemi-ablation of unilateral PCa, as there was high cancer control and low morbidity. Urinary incontinence and erectile dysfunction affected only 3% and 22% of treated patients, respectively, and while robust randomized controlled trials evaluating the long-term benefits of hemi-ablation and/or smaller-margin focal ablation do not exist yet, the study did show there was a 95% absence of clinically significant cancer at the one year follow-up and that the radical treatment-free survival rate was 89% at two years.

Moreover, data from two long-term studies that examined 538 patients and 1,002 patients showed that 10-year cancer-specific survival rates (CSS) were 99%–100% for low-risk patients, 96%–98% for intermediate-risk patients, and 89%–92% for high-risk patients in whole-gland ablation utilizing HIFU (See Exhibit 6). The results approximate the CSS rates seen from RP that have historically been around 80%–90% for high-risk patients. In addition, HIFU offers an option that can provide a significant reduction in unwanted tissue damage, when compared to RT, while keeping the door open for repeated HIFU treatments.

Meanwhile, AS is commonly rejected by patients, due to fears that the disease will progress, and approximately one-third of patients switch to active therapy options within two to three years. We believe these factors are primary reasons why the well-documented medical tourism took place during the ~10 years prior to HIFU being approved in the U.S.; thousands of men with localized prostate cancer went to international destinations and paid ~$25k out of pocket to be treated.

Exhibit 6: HIFU Cancer-Specific Survival and Treatment Side Effects

Whole-Gland HIFU Ablation 10-Year Data **Hemi-ablation**



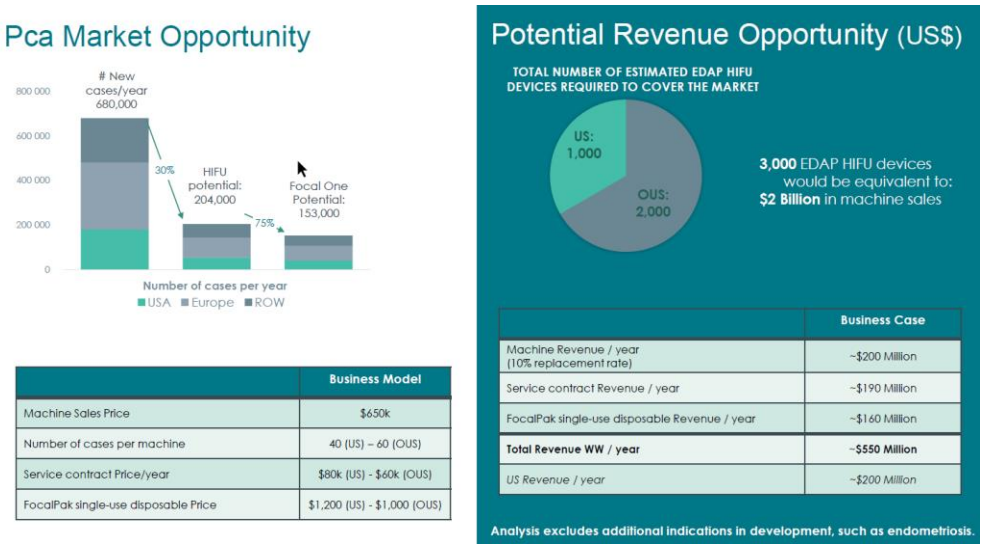
Source: Company reports

We believe PCa offers an immense market opportunity for EDAP. The National Cancer Institute estimates that there were 175k new PCa cases in the U.S. in 2019 and ~3.1M men living with the disease domestically, making it the third most common malignancy. Furthermore, ~77%, or ~135k, of patients diagnosed have localized PCa. Globally, there are an estimated 650k–700k new PCa cases annually.

When considering that ~77% of PCa patients are T-1 and T-2 and that 20%–25% of patients are following AS and 40% of patients fail RT, we believe it is easy to see how HIFU could quickly capture a significant portion of the treatment market, either as an initial active treatment or a salvage therapy. EDAP estimates that 30%, or 204k, of patients are candidates for HIFU globally and that 75% of patients that are candidates for HIFU could benefit from the lesion-specific benefits offered through Focal One.

We believe these total market assumptions could prove to be conservative, as PCa has continued to be diagnosed at an earlier stage over the last 25 years, primarily due to the continued expansion of PSA screening.

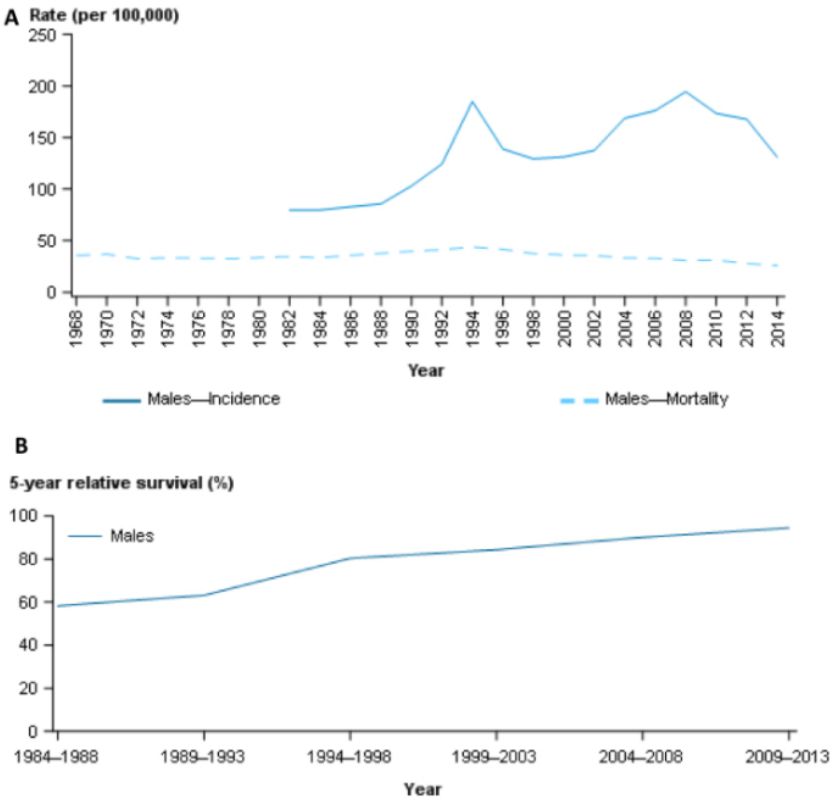
Exhibit 7: HIFU/Focal One Opportunity



	Business Model
Machine Sales Price	$650k
Number of cases per machine	40 (US) – 60 (OUS)
Service contract Price/year	$80k (US) - $60k (OUS)
FocalPak single-use disposable Price	$1,200 (US) - $1,000 (OUS)

Source: Company reports

Exhibit 8: PCa Incidence, Mortality, and Five-Year Survival Rates over Time



Source: [National Center for Biotechnology Information]

We believe headwinds exist for HIFU adoption, as reimbursement has been lacking, and limited comparative studies/long-term treatment benefits have resulted in the American Urological Association (AUA) recommending other treatment options ahead of HIFU. We expect these factors to likely be worked out in the coming quarters and years. For example, although reimbursement has historically been lacking, due to the technology's limited time in the market relative to conventional treatment modalities, and HIFU has been largely paid for out of pocket, progress has been made in recent years. The Centers for Medicare and Medicaid Services (CMS) issued a C code (C9747) for HIFU treatment for PCa. While the code is temporary and only covers facility fees, and recent guidance is teetering on reimbursement between APC 5376 (Level 6) and APC 5375 (Level 5), we expect the CPT code to likely resemble that for cryoablation of the prostate (CPT code 55873), which has a payment rate by CMS of $8.2k.

Meanwhile, with life expectancy for PCa patients increasing, largely because more patients are being diagnosed earlier, patients and physicians are looking for additional options atop the legacy treatment paradigm in an effort to reduce morbidity and improve quality of life. We believe EDAP is favorably positioned to fill this void as the technology class continues to increase its market share and as data from the more than 50k patients that have been treated for PCa by the company's HIFU platform over the last two decades continues to be released. We believe that EDAP's HIFU division could see significant benefits from PCa in coming years, particularly when we consider the real-time imaging advancements and Focal One's ability to enable urologists to ablate diseased tissue with greater precision, potentially further lowering side effects, as well as leading institutions, such as the Mayo Clinic, University of Chicago Medicine, and University of Miami Sylvester Comprehensive Cancer Center, adopting the technology.

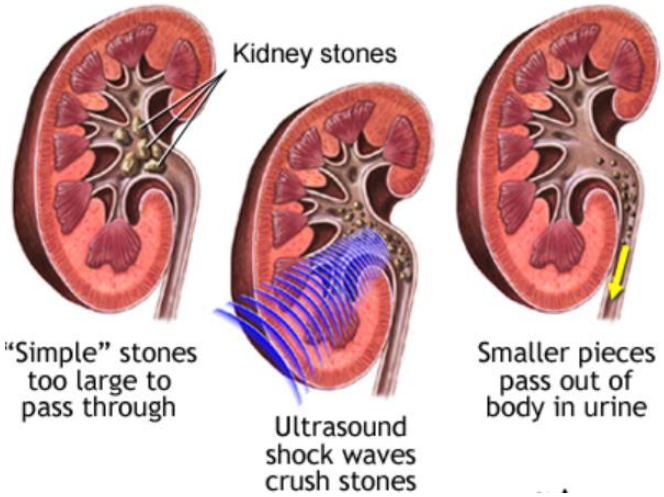
We believe additional upside exists for EDAP's Focal One platform, as the company is looking to expand the technology into new indications. Notably, it is working to expand into deep rectal endometriosis, where the company is working with French regulators to initiate a Phase II clinical trial and is targeting a CE Mark submission for 2021. EDAP is also looking to expand into liver cancer, placenta accrete, and pancreatic cancer, but these are earlier-stage initiatives, with EDAP targeting a 2022 CE Mark submission for liver cancer and the other indications still being evaluated in preclinical R&D. We believe it is likely prudent to assume these time lines will see delays due to the COVID-19 pandemic. Nevertheless, we believe additional indications more than double the opportunity for Focal One and offer meaningful upside to our assumptions, as we do not include in our model any benefits for EDAP expanding its label. Exhibit 9 provides an overview of additional target indications for Focal One.

Exhibit 9: New Focal One Indications

Source: Company reports

Meanwhile, EDAP's UDS division has very different market dynamics. Its core ESWL technology for the treatment of urinary stones is a first-line treatment that has been widely used globally for over 30 years. The division posted 9% Y/Y growth in 2019 and accounted for ~69% of EDAP's sales of €44.9M, down from 72% of 2018's consolidated sales of €39.2M. The business has grown consistently and increased at an 11% CAGR over the last five years, as EDAP has continued to place more units globally and to replace existing systems with new iterations. ESWL is similar to HIFU in many regards, as it utilizes high-intensity, low-frequency pulsating ultrasound waves to produce a shearing force to crush urinary stones (see Exhibit 10). The ultrasound waves are delivered using a lithotripter and are non-invasive.

Exhibit 10: ESWL Fragmenting



Source: U.S. National Library of Medicine

EDAP currently offers two lithotripters, the Sonolith i-sys and the mobile Sonolith i-move (see Exhibit 11). Given the replacement market and continued modernization of healthcare, the product category has been stable for EDAP. The Sonolith i-sys device is primarily dedicated to large clinical facilities, while Sonolith i-move is a modular device designed for smaller centers and ASCs.

Exhibit 11: EDAP's Current ESWL Platforms

ESWL Platform

CE FDA	Sonolith i-move	Sonolith i-sys
Concept System	Fully Modular	Fully Integrated and Robotized
Unique Patented VT	✓	✓
Exclusive ECL Technology	✓	✓
Targeted Customer	ASC & Partnership Model	Large academic institutions
Price Point	$250K-$420k	500K

Source: Company reports

Other first-line treatments have also been available, with lasers being commonly used alongside ESWL. As a result, EDAP's UDS division distributes third-party laser stone management offerings and is in the process of launching Endo-UP, a multisystem stone platform that incorporates multiple stone management modalities. Endo-UP is slated to launch in 2H20E, but because most industry conferences have been suspended due to COVID-19 and uncertainty around when travel restrictions will be lifted, we expect the launch to likely be pushed into 2021.

Exhibit 12: EDAP's Endo-UP

Source: Company reports

Competition

We expect the company's HIFU segment to compete for capital budgeting dollars with companies/equipment that address PCa or are within the broader oncology space, including other PCa-focused HIFU providers like SonaCare and ProFound Medical; radiation oncology med tech companies such as Varian, Elekta, Accuray, ViewRay, iCAD, and Siemens; and Boston Scientific and HealthTronics, which provide cryoablation offerings that are utilized for PCa. The company's UDS segment is in a much more mature market, and ESWL is the first-line therapy for urinary stones. Leading competitors in the space include Dornier MedTech, Richard Wolf GmbH, and Storz Medical.

In both segments, we believe that the market is large enough for sales to be a meaningful growth driver for EDAP. Nevertheless, to profit accordingly, EDAP must, in our opinion, continually innovate, build IP, and establish a beachhead in markets, enabling it to benefit from spare parts/service and disposable revenue streams and better positioning it for potential replacements/upgrades. Management seems to us to be well aware of these factors and appears to be addressing them, which we believe should benefit the company from a competitive standpoint as its latest systems appear to be innovative, industry-leading platforms.

Financial Analysis

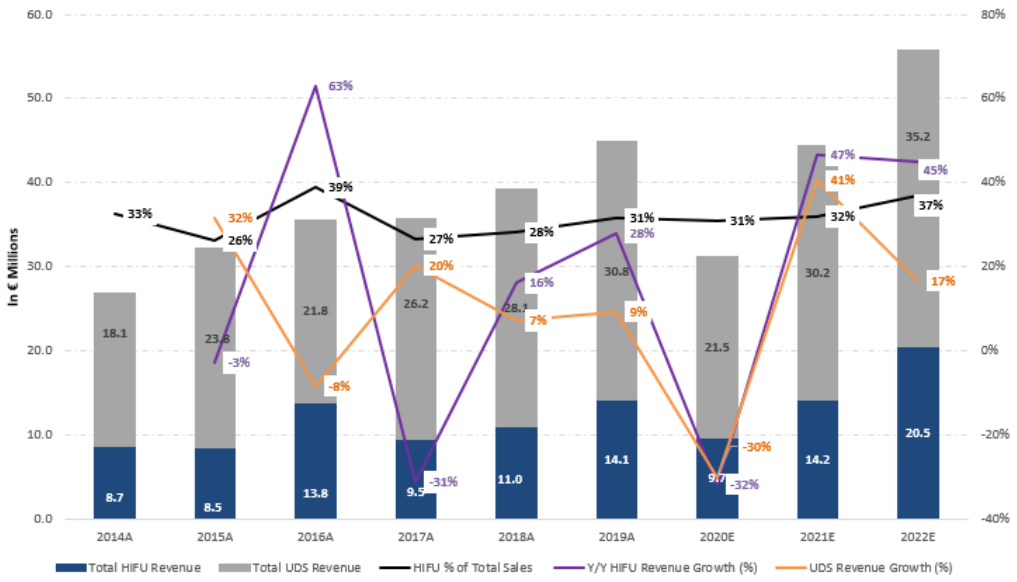
EDAP reported a 2019 top line of €44.9M, up 15% from the year-ago period. This revenue growth was primarily due to stronger HIFU sales, up 28%, as the segment continued to gain traction by placing additional Focal One units and benefited from an increased number of procedures, resulting in stronger disposable and RPP/lease sales. Meanwhile, the company's UDS business increased 9% Y/Y, which is within its normalized annual range. EDAP's gross margin came in at 46.8%, up ~360 bps from 43.2% in 2018, largely due to higher-margin HIFU sales comprising a larger percentage of consolidated sales. EDAP's opex increased €0.6M Y/Y to €18.8M for the year due to increased sales and marketing initiatives. Taken together, EDAP posted net income of €1.5M, compared with (€0.3)M for 2018, which resulted in EPS of (€0.01) and €0.05 for 2018 and 2019, respectively. Adjusted net income and adjusted EPS, which exclude the impact from foreign currency exchange, were (€0.9)M/(€0.03) and €1.4M/€0.05 for 2018 and 2019, respectively. The company exited 2019 with €20.9M in cash and a current ratio of 2.4:1. EDAP had 29M shares outstanding (29.6M on a fully diluted basis) at the end of the year.

2020 and Other Forward Estimates

For 2020, we estimate that sales will decrease to €31.1M, with a GM of 47.2%, with the forecasted sales decline related to the global impact of COVID-19 that we expect to materially hinder operations through the end of 3Q20. We forecast only nominal growth in opex to €19.6M for the year, as we believe that most of EDAP's sales and marketing increases will take place after a CPT code is established for HIFU, which is expected at the beginning of 2021.

We forecast that reimbursement for Focal One will begin in January 2021 and expect HIFU division sales to ramp more rapidly, particularly as we look for sales to rebound following the reduction in global restrictions related to COVID-19. As a result, for 2021 and 2022, we are modeling a top line/adjusted EPS of €44.4M/€0.02 and €55.8/€0.11, respectively. We believe our top-line estimates could prove to be conservative, as our forecasted adoption rates are nominal relative to the market opportunity, in our opinion, and do not take into account the potential expansion of Focal One's label into other indications or significant adoption of Endo-UP.

Exhibit 13: Revenue Breakout by Segment



Source: Company reports and B. Riley FBR Research

Management[1]

Marc Oczachowski, CEO and chairman. Mr. Oczachowski joined EDAP in May 1997 as an area sales manager, based in Lyon, France. From 2001 to 2004, he served as general manager of EDAP Technomed Malaysia and was appointed COO of EDAP TMS in November 2004. In 2007, Mr. Oczachowski was appointed CEO of the company. Prior to EDAP, Mr. Oczachowski worked for Sodem Systems, an orthopedic power tool manufacturer, as an area sales manager. He is a graduate of Institut Commercial de Lyon, France.

François Dietsch, CFO. Mr. Dietsch joined EDAP as its internal audit and consolidation manager in 2005. In 2012, he was promoted to group financial control manager and finance manager of EDAP's French subsidiary, where, in addition to his previous responsibilities, he managed accounting firm relationships at the subsidiary level and was the primary liaison between EDAP and its external auditors. He also managed the finance department at EDAP France. In July 2015, he was promoted to CFO of the company. Prior to joining EDAP, Mr. Dietsch held finance positions at Valeo, a leading global supplier of components and systems to the automotive industry. He holds Master's degrees in management and corporate finance from the University of Paris Dauphine.

[1] *Source: Company reports*

Board of Directors[1]

Philippe Chauveau, director. Mr. Chauveau stepped down as EDAP's chairman in April 2020 and will remain a director until June 2020 when he plans to retire from the board. In 1997, he was named chairman of EDAP TMS S.A.'s supervisory board, which involves a two-tier board structure overseeing an executive board. Both boards were replaced by a single board of directors in 2001, and Mr. Chauveau became chairman and CEO. He remained the company's CEO until 2004. Since 2000, Mr. Chauveau has also been the chairman of SCYNEXIS Inc., a U.S.-based drug discovery company that partners with major pharmaceutical companies. He is also a personal executive coach to senior research leaders at Hoffmann LaRoche in Switzerland. He was R&D VP at AT&T Bell Labs; he had been chairman of Apple Computer Europe, preceded by increasing marketing roles at ITT and Procter & Gamble. Mr. Chauveau has an Honours Degree from Trinity College Dublin with a B.A. and a B.Sc.

Pierre Beysson, director. Mr. Beysson was elected as a member of the board of directors in September 2008 and at the time was the CFO of Compagnie des Wagons-Lits (CWL), the on-board train service division of Accor, a French multinational hotel and business services group. In this capacity, he sat on several boards of companies related to the Accor Group. He is now an M&A consultant. Prior to his assignment at CWL, Mr. Beysson held a number of senior financial positions with Nixdorf Computers, Trane (air conditioning), AM International (office equipment), and FMC (petroleum equipment). Mr. Beysson was trained as a CPA, has auditing experience, and holds an M.B.A. from Harvard Business School.

Dr. Argil Wheelock, director. Dr. Wheelock was elected as a member of EDAP's board of directors in June 2009. Dr. Wheelock, a U.S. board-certified urologist, is currently chief of urology at Erlanger Medical Center, a tertiary care and teaching hospital in Chattanooga, Tennessee. He is chief medical advisor to HealthTronics, a provider of urological services and products in the U.S., which he founded; Dr. Wheelock previously served as the company's chairman and CEO. Dr. Wheelock graduated from the University of Tennessee College of Medicine and completed urological training at Mount Sinai Hospital in New York City.

Rob Michiels, director. Mr. Michiels was elected as a member of EDAP's board of directors in July 2009. He has more than 30 years of U.S. medical device industry experience, both in corporate positions and as a startup entrepreneur. He most recently served as CEO of CardiAQ Valve Technologies, a venture-funded startup developing transcatheter mitral valve implantation, which was acquired by Edwards Lifesciences in 2H15. He previously served as COO of CoreValve (acquired by Medtronic) and as president and COO of InterVentional Technologies (acquired by Boston Scientific). He helped drive both companies from cardiovascular startups to established market leaders, using new and innovative technologies that have strong synergies to the HIFU story. Mr. Michiels is director of Aegis Surgical Ltd., Atrius Ltd., FEops NV, and Embolization Prevention Technologies, all privately held companies developing less invasive cardiovascular technologies. Mr. Michiels is a founding partner of CONSILIUM, a medical device market research company that is active in identifying, funding, and greenhousing start-up technologies. He holds a bachelor's degree in economics from Antwerp University in Belgium and an M.B.A. from Indiana University.

Valuation

We base our $5.50 PT on a 3x EV/sales multiple against our 2021 revenue estimate of €44.4M; we adjust our revenue based on the EUR to USD exchange rates to obtain our per-ADS price target. We believe an EV/sales methodology is most appropriate for EDAP, as the company looks to gain market share within its segments, most notably within its HIFU operations due to Focal One and reimbursement likely coming down the pike shortly. Furthermore, we believe our EV/sales multiple is justified: It is on the low end of other companies in our coverage universe and is a half turn below where our comp group—which includes various oncology and/or ablation technology/equipment companies—is currently trading, despite our assumption that EDAP will grow at a faster rate through our model's time horizon.

Risks

Loss of key distribution partners. A meaningful percentage of EDAP's sales is derived through distribution partnerships. If the company were to lose these partnerships or access to a particular region, our estimates and valuation would likely be materially affected.

Competitive industry. Competition within the urology market is intense, and there are many large companies that could target EDAP's niche, which could materially affect our estimates.

Regulatory risk. There is the risk that EDAP will be unable to receive regulatory approval for next-generation offerings or that regulatory approval may be delayed, which could impact our estimates and valuation.

Adoption. If adoption of EDAP's technologies fails to materialize or does so at a slower rate than we estimate, our valuation could be materially affected.

Financial risk. EDAP is currently in the early stages of its commercialization strategy and may need additional capital in the future to continue research and development programs—and for the commercialization of its products.

Liquidity risk. The company has a relatively small float and a relatively small market cap. Investors could potentially have difficulty finding a liquid market in which to buy or sell shares.

Commercial and other risks. There is commercial risk for EDAP to successfully market and sell its offerings. Other risks for EDAP include financing risk, currency risk, potential governmental price controls, legal, and IP risks. The company could need to raise capital in the future.

EDAP TMS S.A. (EDAP)

FYE: December

Income Statement (€000s except per share data)	2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E
	Dec	Dec	Mar	Jun	Sep	Dec	Dec	Mar	Jun	Sep	Dec	Dec	Dec	Dec
Sales of Goods	22,580	25,070	6,546	8,715	6,878	7,972	30,111	5,891	5,229	4,127	6,776	22,023	32,108	40,558
Revenue-per-Procedures (RPP) and leases	5,095	5,086	1,371	1,429	1,227	1,720	5,747	1,234	500	429	1,462	3,626	4,905	6,451
Sales of spare parts and services	8,011	9,007	2,214	2,342	2,186	2,259	9,001	998	820	765	2,915	5,498	7,346	8,751
Other	59	19	0	0	15	37	52	0	0	0	0	0	0	0
Revenues	**35,745**	**39,182**	**10,131**	**12,486**	**10,306**	**11,988**	**44,911**	**8,123**	**6,549**	**5,321**	**11,153**	**31,146**	**44,359**	**55,760**
Cost of sales	20,937	22,265	5,266	6,155	5,639	6,849	23,909	4,195	3,424	2,843	5,991	16,454	22,623	27,880
Gross Profit	**14,808**	**16,917**	**4,865**	**6,331**	**4,667**	**5,139**	**21,002**	**3,928**	**3,125**	**2,478**	**5,162**	**14,693**	**21,736**	**27,880**
Gross Margin	*41.4%*	*43.2%*	*48.0%*	*50.7%*	*45.3%*	*42.9%*	*46.8%*	*48.4%*	*47.7%*	*46.6%*	*46.3%*	*47.2%*	*49.0%*	*50.0%*
Operating expense														
Research and development	3,881	4,088	1,013	986	886	844	3,728	1,064	1,035	930	886	3,915	4,111	4,317
SG&A	12,954	14,144	3,644	3,691	3,522	4,216	15,074	3,781	3,796	3,811	4,276	15,664	16,904	19,644
Total operating expense	**16,835**	**18,232**	**4,657**	**4,677**	**4,408**	**5,060**	**18,802**	**4,845**	**4,831**	**4,741**	**5,162**	**19,579**	**21,015**	**23,961**
Total expense	**37,772**	**40,497**	**9,923**	**10,832**	**10,047**	**11,909**	**42,711**	**9,040**	**8,255**	**7,584**	**11,154**	**36,033**	**43,639**	**51,841**
Operating income	**(2,027)**	**(1,315)**	**208**	**1,654**	**259**	**79**	**2,200**	**(917)**	**(1,707)**	**(2,263)**	**(0)**	**(4,887)**	**721**	**3,919**
Other income (expense)														
Interest (expense) income, net	2,643	797	(31)	(32)	(40)	(43)	(146)	(43)	(43)	(43)	(43)	(172)	(172)	(172)
Foreign currency exchange gain (loss), net	(909)	538	265	(161)	684	(652)	136	0	0	0	0	0	0	0
Total other income (expense)	**1,734**	**1,335**	**234**	**(193)**	**644**	**(695)**	**(10)**	**(43)**	**(43)**	**(43)**	**(43)**	**(172)**	**(172)**	**(172)**
Earnings before income tax	(293)	20	442	1,461	903	(616)	2,190	(960)	(1,750)	(2,306)	(43)	(5,059)	549	3,747
Income tax (recovery) expense	388	358	115	82	120	362	679	(96)	(175)	(231)	(4)	(506)	55	375
Net income (loss)	**(681)**	**(338)**	**327**	**1,379**	**783**	**(978)**	**1,511**	**(864)**	**(1,575)**	**(2,075)**	**(39)**	**(4,553)**	**494**	**3,373**
Diluted EPS	**(0.02)**	**(0.01)**	**0.01**	**0.05**	**0.03**	**(0.03)**	**0.05**	**(0.03)**	**(0.05)**	**(0.07)**	**(0.00)**	**(0.16)**	**0.02**	**0.11**
Diluted share count	28,962	28,998	29,656	29,605	29,623	29,047	29,620	29,097	29,147	29,197	29,247	29,172	29,972	30,297
Adjusted EPS														
Adjusted net income (loss)	**228**	**(876)**	**62**	**1,540**	**99**	**(326)**	**1,375**	**(864)**	**(1,575)**	**(2,075)**	**(39)**	**(4,553)**	**494**	**3,373**
Adjusted EPS	**0.01**	**(0.03)**	**0.00**	**0.05**	**0.00**	**(0.01)**	**0.05**	**(0.03)**	**(0.05)**	**(0.07)**	**(0.00)**	**(0.16)**	**0.02**	**0.11**
Diluted share count for adjusted EPS	28,962	28,998	29,656	29,605	29,623	29,047	29,620	29,097	29,147	29,197	29,247	29,172	29,972	30,297
Selected Financial Information														
Price (4/13/20)	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23	2.23
Market cap	64,585	64,665	66,133	66,019	66,059	64,775	66,053	64,886	64,998	65,109	65,221	65,054	66,838	67,562
Cash & investments	20,004	19,464	18,555	16,257	17,665	20,886	20,886	24,372	26,183	27,109	21,640	21,640	22,752	29,046
Debt, short and long-term	3,935	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513	5,513
Noncontrolling interests	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Enterprise value	48,516	50,714	53,091	55,275	53,907	49,402	50,680	46,027	44,328	43,514	49,094	48,927	49,599	44,030
Revenue LTM	35,745	39,182	40,155	44,036	46,210	44,911	44,911	42,903	36,966	31,981	31,146	31,146	44,359	55,760
Adjusted EBITDA LTM	(1,248)	1,122	1,536	3,165	4,453	4,235	4,235	4,415	2,746	1,032	1,161	1,161	6,186	8,858
EV/Sales	1.4	1.3	1.3	1.3	1.2	1.1	1.1	1.1	1.2	1.4	1.6	1.6	1.1	0.8
EV/EBITDA	(38.9)	45.2	34.6	17.5	12.1	11.7	12.0	10.4	16.1	42.2	42.3	42.1	8.0	5.0
Y-O-Y revenue growth	**0%**	**10%**	**11%**	**45%**	**27%**	**-10%**	**15%**	**-20%**	**-48%**	**-48%**	**-7%**	**-31%**	**42%**	**26%**

***Numbers may not sum due to rounding**

***Source: Company filings & B. Riley FBR, Inc. estimates**

EDAP TMS S.A. (EDAP)

FYE: December

Common Size (as percentage of net revenues):	2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E
Sales of Goods	63%	64%	65%	70%	67%	66%	67%	73%	80%	78%	61%	71%	72%	73%
Revenue-per-Procedures (RPP) and leases	14%	13%	14%	11%	12%	14%	13%	15%	8%	8%	13%	12%	11%	12%
Sales of spare parts and services	22%	23%	22%	19%	21%	19%	20%	12%	13%	14%	26%	18%	17%	16%
Other	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Revenues	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**
Cost of sales	59%	57%	52%	49%	55%	57%	53%	52%	52%	53%	54%	53%	51%	50%
Gross Profit	**41%**	**43%**	**48%**	**51%**	**45%**	**43%**	**47%**	**48%**	**48%**	**47%**	**46%**	**47%**	**49%**	**50%**
Operating expense														
SG&A	36%	36%	36%	30%	34%	35%	34%	47%	58%	72%	38%	50%	38%	35%
Research and development	11%	10%	10%	8%	9%	7%	8%	13%	16%	17%	8%	13%	9%	8%
General and administrative	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Amortization	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total operating expense	**47%**	**47%**	**46%**	**37%**	**43%**	**42%**	**42%**	**60%**	**74%**	**89%**	**46%**	**63%**	**47%**	**43%**
Total expense	**106%**	**103%**	**98%**	**87%**	**97%**	**99%**	**95%**	**111%**	**126%**	**143%**	**100%**	**116%**	**98%**	**93%**
Operating income	**-6%**	**-3%**	**2%**	**13%**	**3%**	**1%**	**5%**	**-11%**	**-26%**	**-43%**	**0%**	**-16%**	**2%**	**7%**
Other income (expense)														
Interest (expense) income, net	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Interest (expense) income, net	7%	2%	0%	0%	0%	0%	0%	-1%	-1%	-1%	0%	-1%	0%	0%
Total other income (expense)	**5%**	**3%**	**2%**	**-2%**	**6%**	**-6%**	**0%**	**-1%**	**-1%**	**-1%**	**0%**	**-1%**	**0%**	**0%**
Earnings before income tax	-1%	0%	4%	12%	9%	-5%	5%	-12%	-27%	-43%	0%	-16%	1%	7%
Income tax (recovery) expense	1%	1%	1%	1%	1%	3%	2%	-1%	-3%	-4%	0%	-2%	0%	1%
Net income (loss)	**-2%**	**-1%**	**3%**	**11%**	**8%**	**-8%**	**3%**	**-11%**	**-24%**	**-39%**	**0%**	**-15%**	**1%**	**6%**
Net loss at subsidiary attributable to noncontrolling interests	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net income (loss) attributable to common stockholders	**-2%**	**-1%**	**3%**	**11%**	**8%**	**-8%**	**3%**	**-11%**	**-24%**	**-39%**	**0%**	**-15%**	**1%**	**6%**
Adjusted net income (loss)	**1%**	**-2%**	**1%**	**12%**	**1%**	**-3%**	**3%**	**-11%**	**-24%**	**-39%**	**0%**	**-15%**	**1%**	**6%**

***Source: Company filings & B. Riley FBR, Inc. estimates**

EDAP TMS S.A. (EDAP)

FYE: December

Balance Sheet (€000s except per share data)	2017A	2018A	1Q19A	2Q19A	3Q19A	4Q19A	2019A	1Q20E	2Q20E	3Q20E	4Q20E	2020E	2021E	2022E
Total cash	20,004	19,464	18,555	16,257	17,665	20,886	20,886	24,372	26,183	27,109	21,640	21,640	22,752	29,046
Total current assets	39,574	40,376	39,904	40,749	42,383	42,097	42,097	39,974	39,167	37,979	42,475	42,475	48,965	57,869
Total current liabilities	16,134	16,812	16,837	16,357	17,463	17,493	17,493	14,664	13,902	13,296	16,376	16,376	16,908	17,500
Total shareholders' equity	25,158	24,964	25,266	26,780	27,477	27,359	27,359	26,495	24,920	22,845	22,806	22,806	23,300	26,673

*Source: Company filings & B. Riley FBR, Inc. estimates

*Closing price of last trading day immediately prior to the date of this publication unless otherwise indicated.

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Rating	B. Riley FBR Research Distribution [1]	B. Riley FBR Banking Services in the past 12 months[1]
BUY [Buy]	68.93%	30.51%
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(1) As of midnight on the business day immediately prior to the date of this publication.

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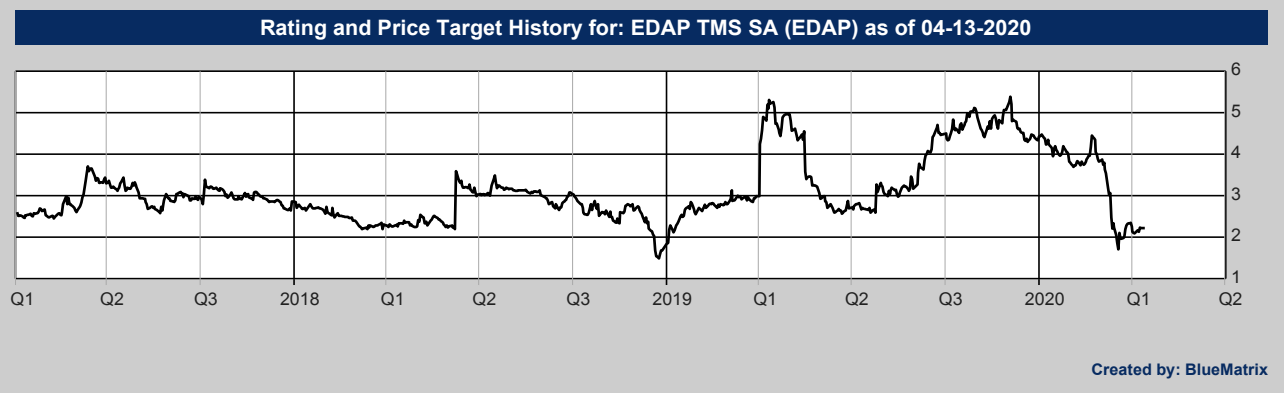
Rating and Price Target History for: EDAP TMS SA (EDAP) as of 04-13-2020
6
5
4
3
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1
Q1
Q2
Q3
2018
Q1
Q2
Q3
2019
Q1
Q2
Q3
2020
Q1
Q2
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