

ASEBIO 2016 REPORT 2016 News and trends from the Spanish Biotech Sector and company guide





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The Spanish biotechnology sector in 2016





The Spanish biotechnology sector in 2016

EXECUTIVE SUMMARY

During 2015 the Spanish economy as a whole saw a continuation of the improvements initiated back in 2014, with growth close to levels not seen since the eve of preceding the financial crisis of 2009.

In this increasingly positive macroeconomic context, biotechnology companies have also consolidated their own path to recovery, with a second year of growth in the total number of companies engaged in biotechnology related activities, which has increased by around 8.7%. The total number has come close matching to the historic highs witnessed during 2011 and 2012, when there were around 3,000 such companies, meaning that just over 2 of every 1,000 companies with employees were engaged in biotechnology activities in 2015.

This growth in the number of companies has also been reflected in terms of economic activity, with increases of around 3% in both turnover and value added, which means that biotechnology activities now account for 4% of GDP in terms of value added.

In dynamic terms, the value added of dedicated biotechnology companies has headed the growth rankings in 2015, reaching nearly 20%, while the increase in nominal GDP growth was 3.7%. The statistics also include, for the first time, the results for the total economic impact of companies active in biotechnology as a proportion of the whole Spanish economy, be it directly, indirectly or induced - an indicator which in 2015 accounted for 8.6% of Spain's GDP and over 930.000 iobs.

The specific contribution of dedicated biotechnology companies reached 8.2 billion euros and 130,000 jobs, around 0.8% of the national total - generating around 3 billion euros in revenue for the public administration. In terms of the whole biotechnology sector, i.e. companies declaring biotechnology activities, either as main or sole activity, second line of business or a tool for production, the biotechnology industry is the direct employer of 182,000 people, having grown by 2.4% in 2015; nevertheless, even after factoring in the growth seen over 2014, the increase did not manage to make up for the sharp fall registered in 2013, as the total number of jobs in the sector failed to reach the numbers seen previously.

1.1. METHODOLOGY

As with other recent reports, the methodology on which the information contained in this section is based on the random sampling method used by the Spanish Statistical Office (INE) for its Survey on Innovation in Companies.

On this occasion, we have further developed the analysis using our own sample of biotechnology companies, from which we have obtained basic accounting records, balance sheets and profit and loss accounts, in order to establish a series of average ratios to further detail the numbers in the INE dataset.

More specifically, a sample of around 70 companies has been used to derive a series of ratios that allow us to collect information comparable to that found in other types of activity; such as Gross Value Added, employee remuneration, gross operating surplus, gross fixed capital formation. Values that have allowed us to carry out a similar study of biotechnology activities *vis-a-vis* other types of activity - and also to carry out an analysis of the overall economic impact that these activities have on the Spanish economy as a whole.

Using the established methodologies for this type of study, it has been possible to establish direct impact in terms of income generation (GDP), employment and tax revenues, as well as the indirect impact from purchases of goods and services by companies engaged in biotechnology activities, and also induced impact, which is derived from both direct salaries and indirect salaries in the sector.

1.2. ANALYSING THE MAIN INDICATORS

As seen on Chart 1, over 2015 there was a change in the falling trend in the total number of companies engaged in biotechnology activities, which had decreased during the previous two years. This time the total rose by around 240 companies, almost reaching the record highs from 2011-2012.

If we compare these numbers to the overall totals for companies with employees in Spain, which in 2015 stood at around 1,447,000, we must conclude that currently two out of every 1,000 companies are engaged in bio-technology related activities, a ratio which has improved slightly after falling for two years

A detailed look at this aspect of business demographics reveals that the biggest increases in relative terms involved companies employing less than 250 employees that use biotechnology as a tool of production, with 13.2% growth compared to the overall average of 8.7%. On the other hand, the number of enterprises for which biotechnology is a secondary line of business continued to fall, with a decrease of over 10%. The number of dedicated biotechnology companies, meanwhile, rose by over 13% during 2013-2014 and more than 4% over 2014-2015.

This increase in the number of companies is reflected in the total number of people employed by the sector, which has risen by 4,183, as the 1,081 jobs lost among companies with over 250 employees were made up for by an increase of over 5,200 jobs among SMEs.

The total volume of business also experienced a small increase during 2015, with turnovers growing by just under 3%, as the rapid growth of up to 10% seen over the past few years started to tail off.

Once more, the dynamics of turnovers across the sector reveal significant differences



2012

Secondary

2013

2014

Tool

2015

CHART 1. EVOLUTION OF THE NUMBER OF COMPANIES ENGAGED IN BIOTECHNOLOGY

2010

Dedicated

2011

190

2009

between segments, with increases of almost 8% for those companies whose primary/exclusive activity involves biotechnology (dedicated biotechnology enterprises) and slight decreases in turnovers among companies using biotechnology as a tool of production.

The data for R&D activities shown on Table 1 suggests a certain increase in activities, as the number of staff hired for R&D activities grew faster than total employment in companies.

Internal spending on R&D rose faster than turnovers, indicating increasing efforts for innovation by enterprises engaged in biotechnology related activities. The increase in R&D spending is particularly marked in terms of capital investment, with increases of over 48%.

Regarding the sources financing for this R&D spending, most funds from outside the EU have shrunk, although the decreases were made up for by Spanish funds, which increased across the board, with the exception of funding from the public administration.



Source: INE. 2015 Survey on Innovation in Companies.



| TABLE 1. MAIN RESULTS FOR BIOTECHNOLOGY | SECTION OF 20 | 15 SURVEY ON II | NOVATION IN | COMPANIES | | |
|---|------------------------|-----------------------|-------------|------------|-----------|-------------|
| MAIN VARIABLES | UNDER 250 Employees | OVER 250 EMPLOYEES | TOTAL 2015 | T0TAL 2014 | VARIATION | GROWTH RATE |
| Companies active in biotechnology | 2,886 | 95 | 2,981 | 2,742 | 239 | 8.72% |
| Dedicated biotechnology companies | 635 | 19 | 654 | 628 | 26 | 4.17% |
| Companies using biotechnology as a second line of business | 202 | 23 | 225 | 250 | -26 | -10.23% |
| Companies using biotechnology as a tool of production | 2,049 | 54 | 2,103 | 1,864 | 239 | 12.80% |
| Companies active in biotechnology R&D | 1,010 | 69 | 1,078 | 1,079 | -1 | -0.07% |
| Total jobs | 74,931 | 107,226 | 182,156 | 177,973 | 4,183 | 2.35% |
| Turnover (millions of euros) (1) | 14,111 | 96,769 | 110,880 | 107,788 | 3,092 | 2.87% |
| Number of biotechnology R&D staff | 7,849 | 2,342 | 10,191 | 9,795 | 396 | 4.04% |
| A) Total by role | | | | | | |
| Researchers | 4,469 | 1,305 | 5,774 | 5,573 | 201 | 3.61% |
| Technicians and assistants | 3,380 | 1,037 | 4,417 | 4,222 | 195 | 4.62% |
| B) Number of women | 4,199 | 1,326 | 5,525 | 5,298 | 227 | 4.28% |
| Researchers | 2,320 | 695 | 3,015 | 2,925 | 89 | 3.05% |
| Technicians and assistants | 1,879 | 631 | 2,511 | 2,373 | 138 | 5.80% |
| Internal expenditure on R&D (thousands of euros) | 441,736 | 136,435 | 578,171 | 533,826 | 44,346 | 8.31% |
| A) Type of expenditure | | | | | | |
| Operating expenses | 387,035 | 130,565 | 517,601 | 492,955 | 24,645 | 5.00% |
| - Salaries for researchers | 158,420 | 55,335 | 213,755 | 203,439 | 10,316 | 5.07% |
| - Salaries for technicians and assistants | 74,027 | 24,413 | 98,440 | 96,850 | 1,590 | 1.64% |
| - Other operating expenses | 154,588 | 50,818 | 205,406 | 192,666 | 12,740 | 6.61% |
| Capital expenditure | 54,701 | 5,870 | 60,570 | 40,870 | 19,700 | 48.20% |
| - Land and buildings | 22,554 | 54.3 | 22,609 | 7,521 | 15,087 | 200.59% |
| - Equipment and devices | 30,685 | 5,483 | 36,169 | 32,078 | 4,090 | 12.75% |
| - Specialised R&D software | 1,461 | 332 | 1,793 | 1,271 | 522.6 | 41.13% |
| B) Sources of funding | | | | | | |
| Funding from Spain | 379,550 | 108,064 | 487,615 | 432,869 | 54,745 | 12.65% |
| - Own funds | 249,391 | 81,068 | 330,459 | 319,046 | 11,413 | 3.58% |
| - Companies | 32,831 | 12,630 | 45,462 | 39,254 | 6,208 | 15.82% |
| - Public funding | 53,162 | 13,028 | 66,189 | 70,063 | -3,874 | -5.53% |
| - Universities | 25,148 | 0 | 25,148 | 156 | 24,992 | 16061.83% |
| - Private non-profit institutions | 19,019 | 1,338 | 20,357 | 4,351 | 16,006 | 367.85% |
| Funding from overseas | 62,186 | 28,371 | 90,556 | 100,956 | -10,400 | -10.30% |
| - EU programmes | 18,782 | 2,150 | 20,932 | 20,070 | 862 | 4.30% |
| - Other overseas funding | 43,403 | 26,221 | 69,624 | 80,886 | -11,262 | -13.92% |

(1) Figures for 2015 have been estimated by ASEBIO from the employment figures.

| TABLE 2. MA | IN SECTOR | INDICATOR | rs by biote | ECHNOLOGY | ACTIVITY IN | 2015 | | | | | |
|--|------------------|------------------|----------------------------|------------------|------------------|----------------------------|------------------|------------------|----------------------------|-------------|-------------|
| | | DEDICATED |) | | SECONDARY | | | TOOL | | TOTAL | TOTAL |
| | VALUE IN 2014 | VALUE IN 2015 | % OVER Total IN 2015 | VALUE IN 2014 | VALUE IN 2015 | % OVER Total IN 2015 | VALUE IN 2014 | VALUE IN 2015 | % OVER Total IN 2015 | IN 2015 | IN 2014 |
| Units active in biotechnology | 628 | 654 | 21.94% | 250 | 225 | 7.54% | 1,864 | 2,103 | 70.52% | 2,981 | 2,742 |
| Units active in biotechnology R&D | 519 | 526 | 48.79% | 179 | 173 | 16.05% | 381 | 379 | 35.16% | 1,078 | 1,079 |
| Number of jobs in biotechnology | 6,911 | 7,255 | 34.56% | 2,142 | 1,891 | 9.01% | 9,522 | 11,847 | 56.43% | 20,993 | 18,575 |
| Expenditure in biotechnology (thousands of euros) | 549,621 | 589,852 | 63.27% | 114,103 | 111,483 | 11.96% | 221,354 | 230,955 | 24.77% | 932,290 | 885,078 |
| Internal R&D expenditure in biotechnology (thousands of euros) | 364,396 | 392,202 | 67.83% | 71,517 | 77,155 | 13.34% | 97,913 | 108,814 | 18.82% | 578,171 | 533,826 |
| Turnover (thousands of euros) ⁽¹⁾ | 7,591,397 | 8,180,667 | 7.38% | 55,566,647 | 58,259,050 | 52.54% | 44,629,922 | 44,440,199 | 40.08% | 110,879,916 | 107,787,966 |
| Total employment | 27,578 | 29,773 | 16.34% | 49,854 | 52,270 | 28.69% | 100,541 | 100,114 | 54.96% | 182,156 | 177,973 |

(1) Turnover figures for companies using biotechnology as a second line or tool in 2015 have been estimated by ASEBIO using the employment figures.

The distribution of the principal sector indicators for the different types of biotechnology activity set out in Table 2 shows that the lead in R&D activities of dedicated biotechnology companies over other types of enterprise remains unchanged, this is reflected by the fact that while they only make up 22% of units engaged in biotechnology, dedicated biotechnology companies account for almost 50% of units carrying out R&D and over 63% of total spending on biotechnology.

If we compare the latest data to that for 2014, it is apparent that there was a certain increase in the percentage of R&D attributed to companies using biotechnology as a tool for production, with increases in total biotechnology-related spending and staff numbers.

Overall, compared to 2014 there were improvements in all the indicators for dedicated biotechnology companies, while the figures

CHART 2. PERCENTAGE OF COMPANIES BY AREA OF FINAL APPLICATION OF BIOTECHNOLOGY



Source: INE. 2015 Survey on Innovation in Companies.



for companies in which biotechnology is a secondary line of business show a certain lack of momentum across all areas except for internal spending on R&D, turnovers and jobs. These last two indicators experienced small decreases compared to 2014 among companies using biotechnology as a tool for production.

The various types of biotechnology enterprise are unevenly distributed in terms of area of final application, with companies using biotechnology as a tool of production being mainly concentrated in the food sector (83.3%) and a large number of dedicated biotechnology companies specialising in the human health area, accounting for nearly 60% of companies in the field.

Companies engaged in biotechnology activities as a secondary line of business show a more homogenous distribution; 38.2% work in the human health area, while 18.9% are active in the industrial biotechnology area.

Comparing to 2014, the biggest changes in terms of the application of biotechnology enterprises is to be found among those applying biotechnology to a secondary activity. Such companies have been increasingly active in the food chain area (agriculture, food and animal health) while there was a fall in applications in the human health area, which was reflected across all types of biotechnology enterprise.

Among dedicated biotechnology enterprises and those companies using biotechnology as a tool of production the pattern is starker still, as the tallies fell across all areas, with the exception of companies working in the food sector.

One of the most significant findings in the 2015 innovation survey was the sharp rise in internal spending on R&D among biotechnology companies, which increased by over 8% overall to \notin 578 million, \notin 10 million more than in 2010 - a record number for this indicator.

All three types of biotechnology enterprise have contributed to this increase, though the greatest relative progress came among companies using biotechnology as a tool for production, with spending increases of over 11%, compared to the 7.6% and 7.9%,



Source: INE. 2015 Survey on Innovation in Companies.

respectively, recorded by dedicated biotechnology companies and those for whom biotechnology is a secondary line of business.

1.3. ECONOMIC EVOLUTION

As mentioned at the start of this section, for the new edition of our report on the trends and current status of the biotechnology sector in Spain, we have been working on redefining the key economic factors for the sector in order to make them more comparable to other activities included in INE data for the various branches of economic activity in Spain.

In this manner and using the figures for total production (turnover) included in our innovation survey and set out in the tables above, we have estimated the purchasing totals required for production (intermediate consumption) from the average ratios set out in the direct survey of biotechnology enterprises to - by using differences - work out the in total added value for enterprises engaged in biotechnology activities.

Also in this manner, and using the data on average salaries from the same direct survey, we established the total remuneration for staff through the rise in the total number of people employed according to the INE innovation survey. Finally, by working out the difference with total value added, we have estimated gross operating surplus for such biotechnology enterprises.

The basic results of these estimates can be found in Table 3.

As can be ascertained from the table above, during 2015, the almost \in 111 billion invoiced by biotechnology related companies required the purchase of about \in 67 billion in intermediate consumption, making the resulting added value around \in 43 billion, of which \in 6.7 billion were allocated to the salaries of 182,156 employees, leaving a surplus of over \in 36 billion.

| TABLE 3. MAIN INDICATORS FOR BI | OTECHNOLOGY CO | MPANIES (MILLI | ONS OF EUROS | AND NUMBER OF | JOBS) | |
|-------------------------------------|----------------|----------------|--------------|---------------|---------|---------|
| | 2015 | 2014 | 2013 | 2012 | 2011 | 2010 |
| Production | 110,880 | 107,788 | 95,152 | 80,313 | 76,069 | 60,122 |
| Dedicated | 8,181 | 7,591 | 7,111 | 8,802 | 7,945 | 8,343 |
| Secondary | 58,259 | 55,567 | 62,494 | 38,387 | 45,360 | 35,125 |
| Tool | 44,440 | 44,630 | 25,547 | 33,124 | 22,764 | 16,653 |
| Intermediate consumption | 67,528 | 65,680 | 54,877 | 49,112 | 44,064 | 33,233 |
| Dedicated | 6,119 | 5,866 | 5,352 | 6,313 | 5,507 | 5,750 |
| Secondary | 31,538 | 29,481 | 32,776 | 20,415 | 23,958 | 18,035 |
| Tool | 29,871 | 30,333 | 16,749 | 22,384 | 14,599 | 9,448 |
| Gross Value Added | 43,352 | 42,108 | 40,275 | 31,201 | 32,005 | 26,889 |
| Dedicated | 2,061 | 1,725 | 1,759 | 2,489 | 2,438 | 2,593 |
| Secondary | 26,721 | 26,086 | 29,718 | 17,973 | 21,402 | 17,090 |
| Tool | 14,570 | 14,297 | 8,798 | 10,739 | 8,165 | 7,205 |
| Compensation of employees | 6,754 | 6,460 | 6,278 | 7,490 | 7,353 | 6,160 |
| Dedicated | 1,250 | 1,064 | 1,199 | 1,520 | 1,391 | 1,750 |
| Secondary | 1,853 | 1,711 | 1,879 | 1,736 | 1,958 | 1,669 |
| Tool | 3,650 | 3,685 | 3,199 | 4,234 | 4,004 | 2,741 |
| Gross operating surplus & net taxes | 36,598 | 35,648 | 33,997 | 23,711 | 24,652 | 20,728 |
| Dedicated | 811 | 661 | 560 | 969 | 1,047 | 844 |
| Secondary | 24,868 | 24,374 | 27,839 | 16,237 | 19,444 | 15,420 |
| Tool | 10,919 | 10,612 | 5,599 | 6,505 | 4,161 | 4,464 |
| Employment | 182,156 | 177,973 | 172,939 | 202,976 | 202,250 | 163,526 |
| Dedicated | 29,773 | 27,578 | 29,621 | 34,827 | 33,183 | 35,917 |
| Secondary | 52,270 | 49,854 | 54,538 | 49,848 | 56,056 | 45,938 |
| Tool | 100,114 | 100,541 | 88,781 | 118,301 | 113,011 | 81,671 |

Source: Own data.

As Table 4 shows, biotechnology companies are, on average, significantly more productive (productivity per employee) than the average for the rest of the economy, and that is particularly true among enterprises for whom biotechnology is a secondary line of business and with just above average salaries.

Their requirements for goods and services are higher, however, making the average added value generated by each unit (% added value over production) lower than average.

Finally, the distribution of income generation (% of salaries incomes and other incomes over added value) clearly leans towards salary incomes in dedicated biotechnology companies; while among those companies using biotechnology as a secondary line of business the opposite is true, reflecting a greater need for capital and lower intensity in labour input.

In dynamic terms, value added created by enterprises engaged in biotechnology has continued to grow systemically to reach 4% of Spain's GDP, mostly (2.5%) attributed to companies for whom biotechnology is a secondary line of business; for companies using biotechnology as a tool of production and dedicated biotechnology companies, meanwhile, it continued at 1.4% and 0.2% respectively.

| | DEDICATED | SECONDARY | TOOL | TOTAL BIOTECHNOLOGY | TOTAL Economy |
|---|-----------|-----------|---------|------------------------|------------------|
| Production in% of GDP | 0.8% | 5.4% | 4.1% | 10.3% | 190% |
| Output per employee (€/person) | 274,764 | 1,114,590 | 443,898 | 608,707 | 110,586 |
| Salary per employee (€/person) | 41,991 | 35,460 | 36,462 | 37,078 | 31,969 |
| % added value as a proportion of production | 25.2% | 45.9% | 32.8% | 39.1% | 47.8% |
| % unearned income | 39.4% | 93.1% | 74.9% | 84.4% | 43.3% |
| % salary income | 60.6% | 6.9% | 25.1% | 15.6% | 56.7% |

Source: Own data.



It is those dedicated biotechnology companies which over 2015 grew most in terms of value added compared to other economic areas, as Chart 5 shows; on the other hand, both companies for whom biotechnology is a secondary line of business and those using it as a tool of production had growth rates slightly below the average.

This contrasts with previous years (2010-2014) when average growth rates for the economy as a whole dipped into negative territory; then user companies (where biotechnology is a secondary line of business or tool) grew by annual averages of over 10%.

In terms of employment, biotechnology related activities have experienced a similar evolution to the rest of the economy over the 'reactivation period' (2014-2015) with average annual growth rates of 2.6%, compared to 2.1% for the Spanish economy as a whole. It should be noted that the sector is still to fully recover from the sharp falls of 2013.



CHART 4. ADDED VALUE IN MILLIONS OF EUROS AND AS PERCENTAGE OF GDP



Source: Own data.



CHART 5. GROWTH RATE FOR VALUE ADDED BY BRANCH OF ACTIVITY IN 2015

Source: INE and own data.





Source: INE.

1.4. ECONOMIC IMPACT OF BIOTECHNOLOGY ENTERPRISES

The availability of more detailed information on the activities of biotechnology related companies has allowed us to carry out an analysis of the economic impact of such activities, one which goes beyond their direct contribution to production, value added and jobs.

Indeed, companies engaged in biotechnology related activities acquire goods and services from other companies, in both running costs and investment, thereby inducing an increase in the growth of those providers, which in turn acquire products from third parties and also contribute to increasing economic activity, jobs and a whole chain of other indirect effects.

Salaries paid by biotechnology related companies, furthermore, as well the incomes of indirectly employed staff, bring about an increase in private spending, leading to additional growth in the economic activity, known as induced (or knock-on) effect.

Finally, all income transactions and those transactions concerning the acquisition of goods and services produced by the activity of biotechnology related companies are subject to a series of taxes, which contribute to increasing the revenues for the public administration; this being known as the fiscal impact.

The estimate of that impact has been reached using the standard methodology based on input-output tables, as Figure 1 illustrates.



Source: Own data.



In aggregate terms, biotechnology companies contributed almost €90 billion, through direct, indirect and induced channels, to Spain's GDP in 2015, around 8.6% of total GDP. Just over 930,000 jobs (5.4% of the total) are the direct or indirect result of activities carried out by such companies. The Public Administration, meanwhile, raised around €26 billion, the equivalent of 2.5% of GDP. As Chart 7 shows, dedicated biotechnology companies contribute around 0.8% of national GDP and employment, a total of \in 8.2 billion in revenues and a total of 130,453 jobs, contributing almost \in 3 billion in revenues for the Public Administration.

CHART 7. ECONOMIC IMPACT OF BIOTECHNOLOGY COMPANIES.



T00L



Source: Own data.

OR IN 2016

1.5. ANALYSIS: AUTONOMOUS COMMUNITIES

As mentioned in previous reports, this section must start by noting that because the methodology used to collect the sample of the innovation survey for enterprises was designed for the country as a whole, the INE underlines that the representativeness of the sample may not be adequate and non-aggregate data for autonomous communities should be interpreted with due caution.

Having clarified that, Chart 8 shows the distribution by autonomous community of the companies engaged on biotechnology activities as a percentage of the national total.

Those communities with the highest levels of economic activity are logically also the ones showing the largest percentages of biotechnology companies, Catalonia is in the lead, with 17.3% of the total, followed by Andalusia (14.7%), Madrid (10.1%) and the Basque Country (8.5%).

If we focus on units using biotechnology as a main line of business, Chart 9 shows the distribution by autonomous community, which, as we can see, is quite similar to that of the previous report, with some notable differences.

Therefore, for instance, the percentage of companies based in the catalane autonomous community has risen sharply, to over 27%. Madrid also rose by a full six points, to just over 16% of the total.

Conversely, there were falls in the percentages for Castile-La Mancha, whose share fell to 0.2% of the total, Castile-Leon, which fell from 7.9% to 4.3% and Galicia, whose share fell from 7.9% for all companies, to 5% for dedicated biotechnology companies.



CHART 8. BIOTECHNOLOGY USER COMPANIES BY AUTONOMOUS COMMUNITY

Source: INE. 2015 Survey on Innovation in Companies.



CHART 9. DEDICATED BIOTECHNOLOGY ENTERPRISES BY AUTONOMOUS COMMUNITY

Source: INE. 2015 Survey on Innovation in Companies and own data.



Companies launched in 2016





Companies launched in 2016

A total of 43 biotechnology companies were registered as having been launched in 2016. All those enterprises, along with a description of the area of activity, are listed on Table 5. When analysing enterprise creation by autonomous communities, it is Andalusia that saw the creation of the largest single number, at 10 new companies, followed by Catalonia with nine, The Basque Country with five and Madrid with four.

TABLE 5. DEDICATED BIOTECHNOLOGY COMPANIES LAUNCHED IN 2016

| COMPANY NAME | AUTONOMOUS COMMUNITY | ACTIVITY |
|----------------------------------|-----------------------|---|
| Abvance Biotech | Madrid | Development of drugs based on antibodies selectively directed at key proteins. |
| Aguettant Ibérica | Catalonia | Pharmaceutical company specialised in the development, production and commercialisation of drugs essential for hospitals and a leader in the development on innovative intravenous drugs. |
| Albajuna Therapeutics | Catalonia | Established to develop monoclonal antibodies to neutralize HIV. |
| Algades | Andalusia | Consultancy and integral management for microalgae production projects. |
| Aora Health | Madrid | Development and commercialisation of nutraceutical products. |
| Asparia Glycomics | Basque Country | Development of glyco analysis solutions for clinical diagnostics and quality control in biopharmaceutical production using molecular characterisation technology. |
| Asturian Biotechnology | Asturias | Animal in vitro fertilisation (IVF). |
| Biodiagsan | Galicia | Diagnostics for animal health and food safety. |
| Bioinsectics | Navarre | Development, production and commercialisation of bioinsecticides. |
| Biopina Biotecnología Industrial | Community of Valencia | Research and development of biotechnology based products for the treatment of natural stone (such as marble) and improvement of characteristics (e.g. toughness, mechanical resistance, colour). |
| Bioprognos | Catalonia | Disease detection based on biomarkers through the development of Multiple Biomarkers Disease Activity Algorithms (MBDAAs) to replace diagnosis and confirmatory diagnostic - thereby reducing the number of biopsies patients must undergo. |
| DNActive | Andalusia | Analysis, diagnostics, prevention and treatment in sports, genetic and nutritional medicine. |
| Ecobium Biotech | Catalonia | Research, development and commercialisation of biostimulant products plants. |
| Empromar | Galicia | Analysis of toxins and tracking of mussel production rafts. |
| Enersos I | Castile-La Mancha | Research and experimental biotechnology development. |
| EverSens | Navarre | Design, development and manufacturing of non-invasive clinical diagnostics systems based on biomarkers. |
| Gistem Research | Asturias | Development of biological products based on uterine stem cells. |
| Green Farm Ticnologies | Community of Valencia | R&D for the development of indoor grow systems. |



| COMPANY NAME | AUTONOMOUS COMMUNITY | ACTIVITY |
|--------------------------|-----------------------|--|
| Green Research | Community of Valencia | Technological development for agriculture and the environment. |
| Ibersens Innova | Castile-La Mancha | Biosensors to measure stress using hormones. Tools for the routine analysis of biomarkers fo animal stress. |
| Idomics Biotech | Basque Country | Application of omic technologies in sports, health and food. |
| Innoprick | Basque Country | Development and commercialisation of a medical device and platform to test for allergies using skin tests. |
| Inymel Biomédica | Andalusia | Production of Melatonin injectables for clinical use. |
| Kiroldna | Basque Country | Development of genetic and sports tests. |
| Laboratorios Edyma | Cantabria | Production and enhancement of in vitro plant culture. Prevention and control of Legionella. |
| Lentistem Biotech | Andalusia | Development of new gene therapy based treatments for rare diseases and cancer. |
| Metabo Stem | Catalonia | This biopharmaceutical company employs METABOSTEM technology to develop oncology drugs specifically designed for the metabolic characteristics of cancer stem cells. |
| Microviable Therapeutics | Asturias | Solutions in the field of human intestinal microbiota. |
| Mideloy | Madrid | Diagnostic detection tests based on the detection of metabolites and / or nucleotides (DNA, RNA). |
| Moirai Biodesign | Catalonia | Design of a new generation of RNA based cancer therapies and diagnostics using 'Plug and Play Biodevice' technology. |
| Natural Extract Oleum | Andalusia | Functional derivatives of olive oil. |
| Nerve Biomed | Andalusia | Biomaterials to be used in regenerative medicine for nerve tissue. |
| Nostrum Biodiscovey | Catalonia | Computational chemistry tools to accelerate, rationalise and optimise small molecule design during early discovery. |
| Patia Diabetes | Basque Country | Design and production of diagnostic kits for gestational diabetes. |
| Pronacera Therapeutics | Andalusia | Services for the improvement of current extracorporeal photopheresis procedures for autoimmune diseases, the development of treatments for lysosomal diseases and clinical analysis. |
| Pump it Nanotech | Catalonia | Nanotechnology and design of bubble removal technology in microfluidic devices for all gravit conditions. |
| Qrem | Catalonia | Development of Qrem system, a one-step automatic device based on cutting edge technology for obtaining autologous cytokines-rich serum from a sample of whole blood. |
| Regemat 3D | Andalusia | Pioneering regenerative medicine based on the use of 3D printing technology in regenerative therapy. |
| Resonantia Laboratorio | Andalusia | Metabolomics and advanced analysis for the food, environmental and materials sector. |
| Rexgenero | Andalusia | Cell therapy with clinical stage products for serious diseases. |
| Saluvet innova | Madrid | Production of ELISA and IFAT antigens from protozoans causing neosporosis, toxoplasmosis and besnoitiosis in ruminants. SALUVET-innova specialises in parasitic and venereal diseases Water analysis for the detection of Cryptosporidium spp. and Giardia spp. among other parasitic agents. |
| Spiral Therapeutics | Catalonia | SPIRAL THERAPEUTICS is focused on finalising preclinical work for the development of pharmaceutical products. |
| StemVital | Cantabria | Collection, processing and cryopreservation of stem cells from blood and umbilical cord tissue. Detection of aneuploidy during prenatal stage. Diagnostic of metabolic disorders in newborns. |

Source: ASEBIO



Business activities



Business activities

3.1. ALLIANCES AND BUSINESS DEVELOPMENT

This section covers business development activities by ASEBIO members. It includes all alliances and/or collaborations in the biotechnology area, for instance co-marketing, co-development, or product/market exchange launched in 2016.

During 2016 a total of 158 alliances were registered. 51.9% of such alliances (Chart 10) involved a partnership with another bio-technology company, organisation or other entity, 51.27% involved another type of or-ganisation, such as a public body, foundation or technology centre, while in 25.32% of cases it involved a biotechnology user company.

Over 50% of all alliances involved Spanish companies or organisations (Chart 11), 22.78% were European, 12.03% American and almost 7% were Asian. Chart 12 shows the percentage of alliances for the various objectives. 54.43% were for R&D, 41.14% for clinical developments or field trials, 15.82% involved marketing or distribution agreements, 10.76% production agreements, and 6.96% involved regulation or industrial property rights.

Chart 13 shows the results of the ASEBIO members survey on obstacles for alliances, with this being the fourth year the survey takes place.

CHART 10. ALLIANCES IN THE SPANISH BIOTECHNOLOGY SECTOR IN 2016 BY PROFILE OF PARTNER



Source: ASEBIO.

CHART 11. ALLIANCES IN THE SPANISH BIOTECHNOLOGY SECTOR IN 2016 BY LOCATION OF PARTNER Asia 6.96%



Source: ASEBIO.

CHART 12. ALLIANCES IN THE SPANISH BIOTECHNOLOGY SECTOR IN 2016 BY OBJECTIVE OF THE ALLIANCE



Source: ASEBIO.



CHART 13. BARRIERS TO ALLIANCES ENCOUNTERED BY RESPONDENTS



Source: ASEBIO.

successful alliance, as over 67% of respondents state that they have never experienced such issues. 61.76% answered that the partner was never the one to cancel the process.

Unattractive economic conditions were the main obstacle enterprises encountered when attempting to establish an alliance.

35% of respondents stated that they had come up against this barrier frequently, while 38% stated that they sometimes did so.

50% of respondents stated that incompatibilities in corporate culture proved to be an obstacle sometimes, while 14.71% had experienced it frequently.

Differences in expectations or strategic focus was an obstacle that 55.88% of respondents have identified sometimes, while 14.71% had frequently come up against it.

3.2. PRODUCT LAUNCHES

In 2016 a total of 108 products or services were launched to market by ASEBIO members.

Table 6 shows the complete list of products and services with a description. Chart 14 shows the distribution according to type of biotechnology.

CHART 14. PRODUCTS AND SERVICES LAUNCHED TO MARKET BY ASEBIO MEMBERS IN 2016







| | TS AND SERVICES LAUNCHED TO MARKET BY ASEBIO MEMBERS IN 2016 |
|--------------------------------|--|
| ENTITY | NAME AND DESCRIPTION |
| ABT | Nickel NTA Magnetic Agarose Beads (5%) for small-scale purification of histidine-tagged proteins. |
| ABT | PREPACKED COLUMNS SEPADEXTRAN™ 25 MEDIUM SC, hydrated gel filtration columns designed for rapid and efficient removal of small molecules (salts, dyes, ammonia …). |
| Alternative Gene Expression | CrisBio: innovative technology platform production of recombinant proteins using Baculovirus and insect pupae as a host. |
| AMGEN | Repatha® biodrug is for the treatment of High LDL Cholesterol in high-risk patients. |
| AMGEN | KYPROLIS Treatment option for people who have already received 1 or more previous treatments for relapsed multiple myeloma. |
| 3BD BioPhenix Biobide | Zebrafish based method to detect the capability of a compound to inhibit angiogenesis as part of efficacy pharmacology studies. |
| 3BD BioPhenix Biobide | Melanin quantification assay to evaluate whitening capabilities of cosmetic product using zebrafish embryo model. |
| 3BD BioPhenix Biobide | Efficacy assay using zebrafish model to evaluate antioxidant capabilities of cosmetic products. |
| 3BD BioPhenix Biobide | Ecotox assay: Fish Embryo Acute Toxicity (FET) Test (Danio rerio). |
| 3BD BioPhenix Biobide | Ecotox assay: Fish, Early-life Stage Toxicity Test (Danio rerio). |
| 3BD BioPhenix Biobide | Ecotox assay: Fish, Acute Toxicity Test. |
| BD BioPhenix Biobide | Ecotox assay: Daphnia sp. Acute Immobilisation Test. |
| 3BD BioPhenix Biobide | Ecotox assay: Freshwater Alga and Cyanobacteria, Growth Inhibition Test. |
| Bicosome | Bicomide S Control: sebum control, acne control. |
| Bicosome | Bicocalm skin: anti-irritation skin balm. |
| Bicosome | Bico Youth CC: Anti Aging Vitamin C Serum. |
| Biochemize | Chemical and microbiology analysis services. |
| Biochemize | Platform for microbial hydroxylation of chemical structures. |
| Biochemize | Platform for enzymatic Enzymatic Carbon–Carbon Bond Formation in chemical structures. |
| Biogen | Flixabi: Remicade biosimilar for Crohn's disease, rheumatoid arthritis, psoriasis, ulcerative colitis, ankylosing spondylitis and psoriatic arthritis. |
| Biogen | Benepali: Etanercept biosimilar for rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. |
| Biogenetics | CanID: technology for genealogical identification of animals and pets. |
| Bioibérica | Nucleoforce Poultry Plus, designed exclusively for use in broilers and layers, adapted to the nucleotides needs of these animals. |
| Bioibérica | Nucleoforce Swine has a specific nucleotide profile that, when applied directly or mixed in with the sow's feed, allows the suckling pigs to incorporate nucleotides through the mother's milk to maintain the immune system and the intestinal mucosa. The product has a minimum concentration of available nucleotides of 90%. |
| Bioibérica | Atopivet®: is a veterinary product for dogs with atopic dermatitis, which helps to re-establish and maintain the integrity of the epidermal barrier. |
| Bioibérica | Hialsorb Cold: cream based on chondroitin sulfate, hyaluronic acid and menthol reduces joint pain and relieves inflammation. |
| Bioibérica | Articolágeno®: innovative food supplement based on collagen, magnesium, vitamin C and Mobilee® for joints, muscles and bones. |
| Biokit | Turbidimetric CRP-Ultrasensitive Test: for use in automated clinical chemistry systems for the precise measuring of C-sensitive proteir (Ultrasensitive CRP). |
| Biokit | Chemiluminescence vWF:CB Test: Von Willebrand Collagen Binding Assay. |
| Biokit | Chemiluminescence HSV-2 IgG: Fully automated chemiluminescent two-step immunoassay for qualitative measurement of IgG antibodies to Herpes Simplex Virus type 1 in human serum or plasma. |
| | |
| Biokit | Chemiluminescence HSV-1 IgG test: for qualitative detection of IgG antibodies to Herpes Simplex Virus type 1 in human serum or plasma. |



| TABLE 6. PRODUC | TS AND SERVICES LAUNCHED TO MARKET BY ASEBIO MEMBERS IN 2016 (CONT.) |
|--------------------------------|---|
| ENTITY | NAME AND DESCRIPTION |
| Biokit | Chemiluminescence VZV IgG test: for the quantitative determination of specific IgG antibodies to varicella-zoster virus (VZV) in human serum or plasma samples. |
| Biokit | Chemiluminescence HTLVI/II test: for qualitative detection of antibodies to HTLV-I and HTLV-II in human serum or plasma. |
| Biokit | Chemiluminescence HBeAg test: for the qualitative determination of the hepatitis B e-antigen (HBeAg) in human serum and plasma. |
| Biokit | Chemiluminescence anti-HBe test: for the quantitative determination of Anti-HBe concentration in human serum and plasma. |
| Biokit | Chemiluminescence HIV combo test: HIV assay for the simultaneous identification of antigens and antibodies for HIV 1 and 2 (HIV I/II Ag/ Ab). |
| Biomedal | New kits using non-invasive test to monitor adherence to gluten-free diet through the detection of gluten immunogenic peptides. |
| Biorizon Biotech | Extraction process of antioxidants from microalgae and macroalgae for use in skin products. |
| Biorizon Biotech | Gama Microtech: range of products developed using enzymatic catalysis of the Spirulina microalgae. |
| BTI Biotechnology Institute | Clinical Support Bti Apnia: system of diagnosis and treatment for sleep apnoea and snoring. |
| BTI Biotechnology Institute | Transepitelial Unit: non-rotating transepithelial pillar for dental implants. |
| BTI Biotechnology Institute | Single-use eye surgery kit (KMU18): for ophthalmological surgery. Combines autologous membrane rich in growth factors and collyrium Endoret PRGF post-surgery treatment. |
| Canvax Biotech | HigherPurity™ Food DNA Purification Kit: for a reliable, easy and high-quality purification of Total DNA from food samples |
| Canvax Biotech | WideUSE™ Plasmid Midi/Maxiprep Kit: for a fast, simple and efficient routinary isolation of high quality plasmid preparations in Midiprep/ Maxiprep format. |
| Canvax Biotech | AgaPure™ Agarose LE (Standard Agarose): High quality Molecular Biology Grade Agaroses. |
| CELGENE | OTEZLA® (apremilast) immunomodulatory treatment for plaque psoriasis and psoriatic arthritis. |
| DIOMUNE | Provides services including animal models, pharmacokinetic studies and toxicity testing (among others). |
| ENZYMLOGIC | GPCR Binding Kinetics Platform: disruptive technology platform to evaluate the kinetic profile of GPCRs. |
| Era7 Bioinformatics | Microbiome analysis services employing PacBio CCS, MG7 technology and DB7 database to sequence and analyse all regions of the gene. |
| Gendiag - Ferrer inCode | Lipid inCode® is an in vitro diagnostic service that allows, through the complete analysis of seven genes, the genetic diagnosis of the molecular causes behind familial hypercholesterolemia. |
| GENOMICA | NEDxA: automated IVD for HPV genotyping test. |
| GENOMICA | CLART® HPV2 lyophilized: for the detection and genotyping of different types of human Papillomavirus. With lyophilized amplification tubes. |
| GENOMICA | CLART® CMA ALK· ROS1: detection and genetic identification of major chromosomal translocations in ALK and ROS1 genes associated with response to therapy in patients with lung cancer. |
| GENOMICA | CLART® CMA EGFR LB: liquid biopsy based test for detection and genetic identification of point mutations, insertions and deletions in the egfr gene pathway associated to non-small cell lung cancer. |
| GENOMICA | CLART® CMA BRAF · MEK1 · AKT1: detection and differentiation 6-point mutations associated with response to therapy in patients with melanoma. |
| Grupo Farmasierra | Alflorex®: probiotic proven to reduce the most severe symptoms of Irritable Bowel Syndrome including pain, abdominal distention, flatulence, constipation and diarrhea. |
| Grupo Farmasierra | Cremigel Piernas Cansadas TRATADERM® with moisturising agents and plant based active ingredients (red vine extract, hamamelis and Ginkgo Biloba) y crystallised menthol. |
| HEALTH IN CODE | LIMS: Genetics Laboratory Management System. |
| HEALTH IN CODE | Genetic diagnostic services for hereditary cardiovascular diseases. |
| HEALTH IN CODE | Genetic diagnostic services for dyslipidemia and early atherosclerosis. |
| HEALTH IN CODE | Genetic diagnostic services for inherited oncological diseases. |
| HEALTH IN CODE | Genetic diagnostic services for genetic muscle diseases. |
| Histocell | Reoxcare: advanced wound dressing with antioxidant properties for the treatment of hard-to-heal skin wounds. |
| Iden Biotechnology | Development biopesticides programme to identify microbial source as the basis for the development of insecticides, nematicides, fungicides and herbicides using biotechnology processes. |
| IRYCIS | Programme to guarantee correct dosage of radiotherapy to be received by patient in High-Dose Rate Brachytherapy. |
| IRYCIS | Protected composition and methodology for skin regeneration. |
| IRYCIS | Multiple sclerosis diagnostic using IgM bands. |
| IRYCIS | Diagnostic panel to identify hereditary hearing loss. |



| ENTITY | NAME AND DESCRIPTION |
|----------------------------|---|
| Laboratorio LETI | LetiSR probioclean micellar water, makeup remover: cleans, soothes and moisturizes. Contains Lactobacillus Ferment, ferment probiotic with moisturizing properties. |
| Laboratorios Rubió | Testogel is a colourless and clear hydroalcoholic gel containing 1% testosterone for the treatment of male hypogonadism. |
| Life Length | Launch of TAT® 3.5 (Telomere Analysis Technology®) for the measurement of telomeres. ISO 15189 and CLIA (Clinical Laborator Improvement Amendments) accredited. |
| Made of Genes | Personal genomics platform. |
| MSD | KEYTRUDA® (pembrolizumab) anti-PD-1 Immunotherapy for the treatment of advanced melanoma (unresectable or metastatic) as a first line treatment in adults. |
| MSD | Spain launch ZERBAXA® (ceftolozane and tazobactam), new antibiotic for the treatment of complicated intra-abdominal infections and urinary tract infections in adults. |
| NanoMyP® | Tiss®-Link: nanofiber membrane for direct covalent immobilisation of biomolecules. |
| NanoMyP® | Tiss®-Streptavidin: high amount of covalently attached streptavidin for direct immobilisation of bioting-labaled-biomolecules. |
| Noray Bioinformatics | Implementation services. |
| Noray Bioinformatics | NorXplore: group of sophisticated mathematica tools for data exploration, mining, predictive modeling, and visualization. |
| Noray Bioinformatics | NorayDocs: software to facilitate communication between researchers, evaluation committee members and committee coordinators. |
| Promega Biotech Ibérica | T Cell Activation Bioassay (NFAT): genetically engineered Jurkat T cell line that expresses a luciferase reporter (TCR/CD3 Effector Cells) driven by either an NFAT-response element (NFAT-RE) or an IL-2 promoter. |
| Promega Biotech Ibérica | PCR Optimization Kit: contains a portfolio of preformulated, high-quality buffers (A–H) that together cover a spectrum of PCR performance capabilities for endpoint, multiplex, real-time, GC-rich and inhibitor-resistant amplifications. |
| Promega Biotech Ibérica | Maxwell® RSC Cultured Cells DNA Kit: automated DNA purification from mammalian and bacterial cultured cells using Maxwell® RSC Instrument. |
| Promega Biotech Ibérica | Maxwell® RSC Tissue DNA Kit: automated DNA extraction from tissue and using Maxwell® RSC Instrument. |
| Promega Biotech Ibérica | Maxwell® RSC Buccal Swab DNA Kit: automated extraction of DNA from buccal swabs using the Maxwell® RSC Instrument. |
| Promega Biotech Ibérica | Maxwell® RSC Stabilized Saliva DNA Kit: for automated DNA extraction from stabilized saliva samples using the Maxwell® RSC Instrument. |
| Promega Biotech Ibérica | GenePrint® 24 System: 24-Locus STR system to generate a multilocus human DNA profile from a variety of human-derived biological sources. |
| Promega Biotech Ibérica | NanoBRET™ TE Intracellular HDAC Assay: the NanoBRET™ Target Engagement (TE) Assay measures compound binding at select target HDAC proteins in intact cells. The assay uses bioluminescence resonance energy transfer to directly measure compound binding affinity as well as compound-target residence time. |
| Promega Biotech Ibérica | Glucose Uptake-Glo™ Assay: a homogeneous bioluminescence, non-radioactive method for measuring glucose uptake in cells, based on the detection of 2-deoxyglucose-6-phosphate (2DG6P). |
| Promega Biotech Ibérica | PowerPlex® 18D System: 18D System is a multiplex STR system for use in database and paternity testing. This system is optimized for direct amplification of samples on FTA®. |
| Promega Biotech bérica | PowerPlex® Fusion System: Co-Amplification and Fluorescent Detection of 24 Loci. Delivers more information and high success rates from demanding forensic, paternity and relationship-testing cases. |
| Promega Biotech bérica | Maxwell® RSC PureFood GMO and Authentication Kit: easy and automated method for efficient purification of DNA used in PCR-based testing for Genetically Modified Organism, DNA sequences and PCR based food and ingredient authentication. |
| Promega Biotech Ibérica | MTase-Glo™ Methyltransferase Assay: bioluminescence-based assay that can be used to monitor the activities of methyltransferases (MTases) and their modulation by small molecules in many applications, including high-throughput screening. |
| Promega Biotech bérica | PD-1/PD-L1 Blockade Bioassay: immune inhibitory receptor expressed on activated T cells and B cells that plays a critical role in regulating immune responses to tumor antigens and autoantigens. |
| Promega Biotech bérica | ReliaPrep™ miRNA Cell and Tissue Miniprep System: isolates total RNA including microRNA (miRNA) and other small non-coding RNA (sncRNA) subspecies from a variety of cell and tissue types within 40 minutes. |
| Roche Farma | Available in Spain: Erivedge® (VISMODEGIB) - first drug for advanced basal cell carcinoma. |
| Roche Farma | Launched Molecular Information Unit with the objective of providing molecular information from tumour genome analysis and the identification of selective potential treatments, which have already been approved, or those under clinical development, as well as clinical trials. |
| Roche Farma | Available in Spain: Avastin® (Bevacizumab), first biologic for advanced cervical cancer. |
| Roche Farma | Cotellic® (Cobimetinib) combined with Zelboraf® for advanced melanoma. |



| TABLE 6. PRODUCT | 'S AND SERVICES LAUNCHED TO MARKET BY ASEBIO MEMBERS IN 2016 (CONT.) |
|----------------------|--|
| ENTITY | NAME AND DESCRIPTION |
| Sanofi | Toujeo® (insulin glargine [from recombinant DNA] injection pen, 300 U/ml), latest generation basal insulin for the treatment of diabetes mellitus types 1 and 2. |
| Sartorius | FlexAct® BT: Single use Bag Tester solution at point of use. |
| Sartorius | SARTOFLOW® Smart: modular and flexible small scale benchtop crossflow system optimized for ultrafiltration and diafiltration applications used in many downstream processes, such as purification of vaccines, monoclonal antibodies and recombinant proteins. |
| SECUGEN | "In house" test to detect the presence of CFH and CFI autoantibodies in patients with complement pathway deregulation. |
| StemTek Therapeutics | Cell2Sphere Kit: 3D cell culture kit for cancer stem cell research, drug development and personalised medicine. |
| Sygnis | SunScript™ One Step RT-qPCR: detect expressed genes in single step process. |
| Vytrus Biotech | Centella reversa, anti-aging: cosmetic ingredients rejuvenate signs of ageing. |
| Vytrus Biotech | Capilia longa, cosmetic ingredient to increase capillary density and reduce hair loss. |
| Vytrus Biotech | Phyto Peptidic Fractions ™ (PPF) shows revolutionary properties for skin regeneration. |

Source: ASEBIO

3.3. STRATEGIC PRIORITIES

This section explores the priorities of member companies and organisations for 2017 and how they have changed since last year.

For the first time since 2008, internationalisation is no longer the main priority for the entities participating in the survey. This year it is product launches that top the list, while internationalisation slips to second.

Expanding operations to other areas of business and refocusing product development are the two priorities which have changed the most since last year, with the former rising three places, from ninth in 2016 to seventh this year. Refocusing product development, meanwhile, fell from tenth to 13th position.

Acquiring another company and reducing operations are considered to be the lowest priority objectives by the entities participating in this survey.

| TABLE 7. ST | RATEGIC PRIORITIES AMONG BIOTECHNOLOGY COMPANIES IN 2017 | | | | |
|-----------------|--|-------------------|-----------------|------------------|----|
| 2017 Ranking | PRIORITY | RELEVANCE 2017 | 2016 Ranking | CHANGE C To 2 | |
| 1 | Launch of products to market | 3.20 | 3 | A | 2 |
| 2 | Internationalisation | 2.94 | 1 | ▼ | -1 |
| 3 | Acquiring knowledge and/or technology | 2.61 | 2 | • | -1 |
| 4 | Initiating clinical phases/field trials/dose scaling | 2.12 | 4 | /=/ | 0 |
| 5 | Alliances with user companies (pharma, food) | 2.10 | 5 | /=/ | 0 |
| 6 | Expanding into other business areas | 1.84 | 9 | | 3 |
| 7 | Licensing out technology | 1.67 | 6 | ▼ | -1 |
| 8 | Contracts or alliances with public institutions | 1.65 | 7 | ▼ | -1 |
| 9 | Alliances with dedicated biotechnology companies | 1.63 | 8 | ▼ | -1 |
| 10 | Hiring overseas professionals | 1.35 | 11 | | 1 |
| 11 | Setting up joint venture | 1.16 | 13 | | 2 |
| 12 | Refocusing R&D activities | 1.10 | 12 | /=/ | 0 |
| 13 | Refocusing product development | 1.08 | 10 | ▼ | -3 |
| 14 | Licensing in technology | 0.86 | 14 | /=/ | 0 |
| 15 | Outsourcing production | 0.71 | 15 | /=/ | 0 |
| 16 | Merging with another company | 0.51 | 16 | /=/ | 0 |
| 17 | Acquiring another company | 0.35 | 18 | | 1 |
| 18 | Reducing operations | 0.29 | 17 | ▼ | -1 |

Source: ASEBIO.



Industrial property rights and knowledge generation





Industrial property rights and knowledge generation

The data used for this Technology Watch Report was gathered following a methodology designed by Clarke, Modet & Co and Madrid Science Park and is based on OECD definitions for the biotechnology sector. This methodology has been specifically designed for this use and is continuously improved by building upon the experience from studies on Industrial Property Rights conducted in previous years.

This report has been compiled using data sourced from Thomson Reuters. Other public databases used for data contrasting purposes include: the Spanish Trademark and Patent Office (SPTO), the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), Japan Patent Office (JPO) and the World Intellectual Property Organization (WIPO). Data from all of the institutions above is based on patent publications.

PATENT APPLICATIONS PUBLISHED AND PATENTS GRANTED

A total of 813 biotechnology sector patents were published in Spain during 2016 (data sourced from published Spanish patents for bio sector, PCT, EP, US and JP, prioritising Spanish or Spanish agent and Spanish client), a small decrease of 11% compared to 2015, like last year it is a similar number to that of 2013 (when 901 patents were published). 62% of patents published were patent applications and the remaining 38% were patents granted. Table 8 breaks the numbers down according to the patent protection obtained. Chart 15 shows that the largest percentage of published applications went through EPO and PCT, each accounting for 65% of the total, followed by applications to OEPM and USPTO. The distribution has remained practically the same since 2013.

Chart 16 shows that the largest percentage of patents granted was, like the previous year, processed by the OEPM, with 46% of the total. Compared to 2015, the number of US patents granted fell slightly, from 12% in 2015 to 10% in 2016.

| TABLE 8. NUMBER OF PATENT APPLICATIONS AND PATENTS GRANTED TO SPANISH BIOTECHNOLOGY ENTITIES (2016) | | | | | | |
|--|------|-----|-------|------|-------|-------|
| Patents published 2016 | OEPM | EPO | USPTO | JPT0 | PCT | TOTAL |
| Applications | 103 | 190 | 53 | 21 | 135 | 502 |
| Granted | 143 | 117 | 31 | 20 | (N/A) | 311 |
| TOTAL | 318 | 307 | 84 | 41 | 62 | 813 |

Source: Clarke & Modet – PCM.



Source: Clarke & Modet - PCM.





46%

4.1. PATENT OWNERSHIP IN 2016

During 2016 the business sector regained its position as the biggest agent in Spain, as it was in 2014. This year co-ownership was the most popular option, accounting for 36% of patents published, followed by the business sector (30%) and universities (19%). This trend in ownership is reflected both in the number of applications and patents granted (see Chart 17).

4.2. COMPANY PATENTS IN 2016

Over the course of 2016 a total of 125 biotechnology companies published 152 patent applications and had 111 patents granted, a decrease, as in 2015 a total of 152 companies published 184 patent applications and had 97 patents granted.

Like in 2015, Grifols published the largest number of patents, followed by ABENGOA and Lipotec. Neol Biosolutions closed the gap with six patents published, while Repsol published five.

4.3. INDUSTRIAL PROPERTY IN THE SPANISH BIOTECHNOLOGY SECTOR: 2009-2016

According to data published over eight years, the number of patent publications in the biotechnology sector is following a clear growth trend, with 89% growth over the 2009-2016 period. This evolution reflects weaker growth in the sector, as cumulative growth was lower than during the 2009-2014 and 2009-2015 periods. Compared to 2015, there was a decrease of almost 10% in both applications published and patents granted. The decrease in publications follows continues the trend from 2014, though it is more marked in patent applications.

Chart 19 tracks the evolution of biotechnology sector patents published in Spain,



CHART 17. OWNERSHIP OF PATENT APPLICATIONS AND PATENTS GRANTED (2016)

Source: Clarke & Modet – PCM.





Source: Clarke & Modet - PCM.

showing a slight decrease in the total number of publications during 2015 and 2016. The growth trends seen during 2012 and 2014 have not been repeated in 2016, except in terms of european patents, for which the number of patents published has risen again. OEPM patents have fallen in terms of numbers, though again the decrease is partly made up for by the increase in european patents.



4.4. SCIENTIFIC OUTPUT – BIOTECHNOLOGY COMPANIES

Every year, ASEBIO carries out a study of publications in high impact journals by Spanish biotechnology companies and international research laboratories based in Spain that are members of ASEBIO.

The study does not include press releases, conference posters, poster presentations, or publications by research centres or universities without links to studies for business projects.

Over the course of 2016 a total of 163 scientific papers were published by 32 biotechnology companies.

The companies with the largest number publications (Chart 20) included BTI Biotechnology Institute with 33 papers, Pharmamar with 19, Pangea Oncology at 16. These companies were followed by promega Biotech with 14 publications, Bioiberica at 11 and AMGEN with 9.



CHART 19. TRENDS IN PATENT PUBLICATIONS (2009-2016)

Source: Clarke & Modet – PCM.



CHART 20. NUMBER OF SCIENTIFIC PUBLICATIONS BY ASEBIO MEMBERS IN 2016

Demonstration of new natural dyes from algae as substitution of synthetic dyes actually used by textile industries.



SEACOLORS project main aim was the demonstration and validation of obtaining natural dyes from a sustainable and renewable source, algae and their application in textile industry to replace synthetic dyes which are pollutant and harmful for the environment.

In order to achieve the proposed objectives, several phases were accomplished:

ALGAE with high yield of colorants were studied and selected:



ENVIRONMENTAL CONDISERATIONS:

The obtained results can lead to a substitution in the use of synthetic chemicals (Dye-stuffs) by a natural and renewable source, that can turn dyeing into a more ecofriendly and economic procedure, specially regarding wastewater disposal, CO, generation (in the synthetic dyes production), energy and water consume.









asebio


Spanish biotechnology sector milestones in 2016





Spanish biotechnology sector milestones in 2016

This section lists the most significant milestones among ASEBIO member companies in 2016.

January

| Patent granted | AB Biotics | During 2016 patents were granted for I3.1 in the Philippines and China for AB Fortis in Chile and Guatemala, for AB Life in Russia, Japan, Indonesia and Peru and for AB Dentalac in Japan, China and the US. |
|-------------------------|---|---|
| Patent Granted | Biosearch Life | European patent granted for the use of probiotics to treat mastitis. |
| Product launch | Celgene | Launch of OTEZLA $\ensuremath{\textcircled{B}}$ (apremilast), the first PDE4 inhibitor for the treatment of psoriasis and psoriatic arthritis. |
| Study launch | Era7and Health in Code | Lauch of CARDIOBIOME project: development of bioinformatics platform integrated with the Electronic Health Record for human microbiome analysis. |
| Patent granted | Fina Biotech | Two new patents granted in the US and Canada patent family "bladder cancer diagnosis and/or prognosis method". |
| Product launch | Genomica | Product launch: CLART® CMA EGFR BL liquid biopsy in non microcytic lung cancer CLART® CMA BRAF MEK1 AKT1 Detection oncogene mutations associated melanoma, CLART® CMA ALK ROS Detection and genetic identification of major chromosomal translocations associated with response to therapy in patients with lung cancer. |
| Distribution agreement | Grifols | Acquired exclusive rights to commercialise and distribute MassBiologics vaccine for tetanus and diphtheria in the US. |
| Study launch | Grupo Praxis Pharmaceutical | Project launch: new therapeutic approaches for the treatment of cystic fibrosis based on small transmembrane transporter-class ion molecules. |
| Product launch | MSD | KEYTRUDA® (pembrolizumab), an anti–PD-1 Immunotherapy, is now available on the Spanish Health System for the treatment of advanced melanoma (unresectable or metastatic) in adults. |
| Product launch | NanoMyP® | LanzaTiss®-Link, a nanofiber membrane for direct covalent immobilisation of biomolecules and Tiss®-Streptavidin, High amount of covalently attached streptavidin for direct immobilisation of bioting-labaled-biomolecules. |
| Study launch | Sistemas Genómicos | Joined new european project (Liqbiopsens): detection of KRAS and BRAF mutations in colorectal cancer using blood liquid biopsy. |
| Study launch | Spherium Biomed Efficacy trial for SP12006 for the treatment of acute pain in patients with Temporomandibular Joint Disorders (TMJD). | |
| Presentation of results | TiGenix | Announced positive results in ADMIRE-CD study for the treatment of Perianal Fistulizing in patients with Crohn's Disease. |



February

| Product launch | Amgen | Repatha® (evolocumab) is available through the Spanish Health System as the first biodrug for hypercholesterolemia in patients who need additional lowering of LDL cholesterol in spite of taking a statin. |
|---------------------|--|---|
| Study concluded | Centro de Genómica e Investigación Oncológica (GENyO) - Parque Tecnológico de la Salud (PTS) | Blood test for the identification of metastasis-initiating cells and evaluation of treatments as they are being applied (without having to wait for their effects). |
| Startup | Inkemia-IUCT | Launch of subsidiary: InKemia Green Chemicals Inc. in the US. |
| Product approval | Novo Nordisk Degludec insulin received approval in SPain. Innovative and long lasting basal insulin analogue. | |
| Study launch | PharmaMar | Announced the start of an open-label multi-centre two-stage Phase II trial to evaluate the efficacy and safety of anti-tumour drug PM184 for advanced breast cancer. |
| Licensing agreement | PharmaMar | PharmaMar and Specialised Therapeutics Asia Sign Licensing and Marketing Agreement for APLIDIN® (plitidepsin) Covering Several Asian Countries. |
| Regulatory approval | Roche Farma | The FDA approved multiple sclerosis drug ocrelizumab for primary progressive form of the neurological disease (PPMS). The drug also received the FDA's NME Classification. |
| Study launch | Sistemas Genómicos Joins Desiree Project: a web-based software ecosystem for the personalised and multidisciplinary management of primary breast cancer, improving diag treatment. | |
| Product launch | Sygnis | Global launch of SunScript [™] One Step RT-qPCR Kit. The product allows both transcription and amplification of genomic DNA in a one-step reaction that can be measured in real time. |
| Product approval | TiGenix Obtained license for commercial production of Cx601 for the treatment of c fistulas in Crohn's disease patients. | |
| Study launch | VCN Bioscience Independent Phase I dose escalation clinical trials with VCN-01 for pati cancer. | |
| | | |

March

| Product launch | Biogenetics | Launch of CanID, an innovative technique to identify using their DNA. |
|---------------------|--------------------|---|
| Study results | CIBER | Collaboration with other Spanish entities to develop laboratory-scale nanodevices for the controlled release of drugs in breast cancer therapies. |
| Research agreement | Iden Biotechnology | New collaboration with Bioceres to develop GM wheat resistant to low temperature. |
| Study launch | InKemia-IUCT | Launch of Myo-DM1 project: development of food supplements to improve the quality of life of patients suffering from Myotonic Distrophy type 1 (DM1). |
| Study results | Lipopharma | Results for Phase I/lla clinical study for Minerval in patients with advanced cancer. |
| Research agreement | mAbxience | Selected by the WHO and The Utrecht Centre of Excellence for Affordable Biotherapeutics for Public Health (UCAB) to lead the project aimed at developing Palivizumab biosimilar (Synagis®). |
| Regulatory approval | PharmaMar | Regulatory authorities in 6 countries have granted 10 new authorisations to sell Yondelis®, these are: Saudi Arabia, Moldova, Bangladesh, Brunei, Costa Rica and Kuwait. |
| Study results | Sylentis | Sylentis reports positive Phase II results with SYL1001 in treating ocular pain related to dry eye syndrome. |
| Product launch | Vytrus Biotech | Launched Phyto-Peptidic Fractions [™] : first generation active cosmetics able to maintain the skin's regenerative potential. |



April

| Study launch | Genmedica Therapeutics | Announced the start of a Phase lb multiple ascending dose clinical trial in type 2 diabetes patients that do not respond adequately to metformin monotherapy. |
|---------------------|------------------------|---|
| Acquisition | Grupo Bionaturis | Acquisition of Zera Intein Protein Solutions, company specialised in the development of technologies for the production of peptides and recombinant proteins. |
| Regulatory approval | Merck | New liquid biopsy OncoBEAM® RAS CRC test has been granted CE Mark approval. It was developed by Sysmex Inostics in collaboration with Merck and will be commercialised by both companies. |
| Product launch | MSD | MSD launched ZERBAXA $\ensuremath{\mathfrak{B}}$ (ceftolozane and tazobactam) in Spain, an antibiotic for the treatment of complicated intra-abdominal infections and urinary tract infections in adults. |
| Research agreement | Pangaea Oncology | Long term agreement to launch in the U.S.A and China a non-invasive test to detect genetic material in blood of cancer patients. |
| Regulatory approval | Roche Farma | FDA approved Gazyvaro ${}^{l\!$ |
| Product launch | Sanofi | Launched Toujeo $^{(\!$ |
| Financing | Stat Diangostica | Closed funding round for € 25 million. |
| | | |

May

| Licensing agreement | Ability Pharmaceuticals | Licensing agreement with SciClone Pharmaceuticals for its ABTL0812 cancer drug - to be commercialised in China. |
|---------------------|-------------------------|--|
| Research agreement | Almirall y Bicosome | Research, collaboration and sub-licensing agreement for the development of solutions in the skincare filed using the Bicosome® platform. |
| Study launch | Bioibérica | Trial (randomized, double-blind) to evaluate the Efficacy and Safety of new compound to improve memory in patients with mild severity Alzheimer's Disease. |
| Study launch | Canvax Biotech | Launch of FRIDASTEM project: accelerate small molecule drug discovery related to Cancer Stem Cells (CSC) proliferation, migration, invasion or metastasis. |
| Regulatory approval | Histocell | Reoxcare®obtains the CE mark for its commercialisation in Spain, Europe and countries that accept the CE marking, such as Hong Kong, Macau and Chile. |
| Anniversary | Lilly | On the 10 May the company marked 140 years in the pharmaceutical sector. |
| Study concluded | Palobiofarma | Concluded phase Ib clinical trial for new inhibitor - PDE-10 PBF-999. |
| Licensing agreement | Pangaea Oncology | Singing of licensing agreement with Cancer Research Technology to develop p21-activated kinase inhibitor drugs for cancer. Pangaea will assume responsibility for pre-clinical and clinical development. |
| Acquisition | Reig Jofre - Oryzon | Reig Jofre bought 100% of GynEC $\ensuremath{\mathbb{R}}$ -DX from Oryzon - a molecular diagnostic test for the early detection endometrial cancer. |
| Study launch | Sanofi | Cdiffense [™] is a Phase III trial to evaluate the safety, immunogenicity and efficacy of a toxoid vaccine for the prevention of primary symptomatic C. difficile infection (CDI). |



June

| Licensing agreement | Almirall | In-licensed (development and commercialisation) PAT-001 drug from Patagonia Pharmaceuticals. It is a new medicinal treatment containing isotretinoin for the treatment of congenital ichthyosis. |
|---------------------|--------------------|---|
| Study results | Bioibérica | Presentation of results from meta-analysis of two randomized Mobilee studies: stimulates the synthesis of hyaluronic acid, reduction of synovial effusion, joint pain / inflammation and increase in muscle mass and function. |
| Accreditation | Biosearch Life | Received authorization for registration of their probiotic strain <i>Lactobacillus fermentum</i> CECT5716 LC40. Registration allows the inclusion of LC40 in infant formula milk manufactured in China. |
| Study launch | Dreamgenics | Joined GCH-CLL project to work on techniques to predict chronic lymphocytic leukaemia outcome and treatment resistance. |
| Regulatory approval | Grifols | FDA Approved the use of the Procleix Zika Virus Assay from Hologic and Grifols to screen the U.S. Blood Supply under an IND Study Protocol. |
| Startup | Inkemia-IUCT | Set up new UK-based company for advanced and second generation biofuels. |
| Regulatory approval | Laboratorio LETI | European Commission authorises commercialisation of LetiFend, the first vaccination for canine leishmaniasis based on a recombinant protein. |
| Product launch | Laboratorios Rubió | Testogel is a colourless hydroalcoholic gel containing 1% testosterone for the treatment of male hypogonadism. |
| Startup | Neol Bio | Created "Neol Nutricional Products" for the production and commercialisation of its Omega-3 DHA (docosahexaenoic acid). |
| Study launch | PharmaMar | Announced the start of a multicenter, prospective, pivotal study to analyze the efficacy of the antitumoral compound of marine origin plitidepsin (Aplidin®) in patients with relapsed and refractory angioimmunoblastic T-cell lymphoma. |
| Product launch | Reig Jofre | Launched Forté Pharma, a new line of food supplements in Hong Kong and Macao. |
| Product launch | Roche Farma | Erivedge® (VISMODEGIB) has been authorised for sale in Spain for the treatment of It is the first advanced basal-cell carcinoma. |
| Study results | TiGenix | Announced Phase I/II Results of AlloCSC-01 in Acute Myocardial Infarction. |
| Licensing agreement | TiGenix | TiGenix and Takeda enter into licensing agreement for commercialisation (outside US) of Cx601 for the Treatment of Complex Perianal Fistulas in Patients with Crohn's Disease. |
| | | |

July

| Financing | Atrys Health | Atrys Health was listed on the MAB stock exchange. |
|--|----------------------|--|
| Research funding | Biohope | Received €3.8m from Horizon 2020 SME Instrument Phase 2 to develop diagnostic and personalised therapy technology for renal transplants. |
| Product launch | Grupo Farmasierra | Commercialisation in Spain of Alflorex $\ensuremath{\mathbb{B}}$, a probiotic that has proven its efficacy in reducing the symptoms of Irritable Bowel Syndrome. |
| Approval revision commercialisation | Merck | Received EMA approval for the use of Cladribine tablets in the treatment of relapsing forms of multiple sclerosis. |
| Study launch | Minoryx Therapeutics | Initiated Phase I clinical trial in humans with MIN-102 compound. |
| Patent granted | Neuron Bio | The European Patent Office has granted a patent to Neuron Bio for a family of neuroprotective compounds with potential uses in the treatment of neurodegenerative disorders, particularly Alzheimer's disease. |
| Study launch | Oryzon | Oryzon Initiates Multiple Ascending Dose Cohorts In ORY-2001 Phase I clinical trial of its proprietary oral epigenetic drug in healthy subjects. |
| Study launch | Oryzon | Oryzon nominated ORY-3001, a specific LSD1 inhibitor, next drug candidate to enter preclinical development in non-oncological indications. |
| Research agreement | Som Biotech | Announced collaboration with Inorgen to develop new opportunities in Drug Repositioning in Rare Diseases in a number of therapeutic areas. |
| Accreditation | VidaCord | Granted international accreditation by the American Association of Blood Banks. |
| | | |



August

| Study results | Grifols | Presented the results of the Phase I trial for ABvac40, by Araclon Biotech, for Alzheimer's disease. ABvac40 produced an immune response in more than 87% of patients who received the product during the trial. |
|-----------------|--------------|--|
| Study concluded | Palobiofarma | Completed Phase la clinical trial with new adenosine A3 antagonist PBF-677. |
| Study launch | PharmaMar | Announced the start of Phase III ATLANTIS study evaluating the efficacy and safety of PM1183 (lurbinectedin) in combination with doxorubicin versus topotecan or the combination VCR in patients with small cell lung cancer (SCLC) after the failure of one prior platinum-containing line. |

September

| Study results | Almirall | Announced positive results from two Phase III trials of tildrakizumab, as a potential treatment for chronic moderate-to-severe plaque. |
|---------------------|----------------------|--|
| Acquisition | Bayer and Monsanto | Monsanto has agreed to a takeover offer by Bayer under which Bayer will buy Monsanto for \$128 per share in an all-cash deal. |
| Research agreement | Bioibérica | Signed a partnership agreement with the Institute for Bioengineering of Catalonia and the Barcelona Institute for Global Health to study the development of new compounds derived from heparin to combat malaria. |
| Study results | Esteve | First presentation of Phase II clinical studies with MR309 at the 16th World Congress on Pain demonstrate significant clinical benefits of a new analgesic in the treatment of patients with peripheral neuropathy of different aetiologies. |
| Product launch | Ferrer | Commercialisation of UTIPRO PLUS® for the control and prevention of urinary tract infections. The compound is based on Xyloglucan. |
| Research agreement | Ferrer | Created a consortium with the Institute for Bioengineering of Catalonia and the bioinformatics company Mind the Byte to study the development of new therapeutic molecules against cancer metastasis. |
| Study launch | Histocell and Ferrer | First clinical trials for new cell therapy drug to treat spinal cord injuries of traumatic origin - in collaboration with Histocell. |
| Study launch | Life Length | Participated in Horizon 2020 ONCOCHECK project: clinical trials for telomere technology Life Length TAT as a prognosis biomarker in the treatment of cancer. |
| Regulatory approval | PharmaMar | EMA accepted Marketing Authorization Application for Aplidin® (plitidepsin) in combination with dexamethasone for the treatment of relapsed/refractory multiple myeloma. |

October

| Product launch | Amgen | Announced Kyprolis $\ensuremath{\mathbb{B}}$ (carfilzomib) available in Spain for adults with relapsed multiple myeloma. |
|--|------------------------|---|
| Distribution agreement | Bicosome | Announced agreement with Nano Tech Enterprise to commercialise its dermopharmaceutical ingredients and high-performance cosmetics in Africa and the Middle east. |
| Transparency agreement | Diomune | Signed transparency agreement with nearly 90 other public and private institutions on use of animals testing in science research in Spain. The objective being the 'opening up' of laboratories and technology companies, as well as demonstrating the working practices and management standards that must be complied with in the area of animal welfare. The agreement also aims to provide further information about the benefits of these activities for society. |
| Study results | FibroStatin | Announced development of treatment for drug resistant cancer and organ fibrosis using technology to inhibit cell epithelial-to-mesenchymal transition (EMT) an underlying cause in these disorders. |
| Study launch | Grupo Bionaturis | Launched research to translate its vaccine for leishmaniasis to humans. |
| Accreditation | Ingenasa | Registered two new tools: one for Porcine Tuberculosis control and management in wild boars and domestic pigs and a second tool to control the Porcine Epidemic Diarrhoea. |
| Financiación | Lilly | Lilly Global Healh launches 5-year investment plan totalling \$90 million to meet weaknesses in the treatment of diabetes, cancer and tuberculosis. |
| Award | mAbxience | Received the Biosimilar Initiative of the Year prize at the "Global Generics & Biosimilars" awards ceremony organised by British publication "Generics Bulletin". |
| Expansion of capabilities / facilities Merck | | Opened expansion of its new biotechnology plant in Tres Cantos, Madrid, after €15 million investment. |
| Regulatory approval MSD | | Approved Keytruda® (pembrolizumab) as first line treatment for patients with metastatic non-small cell lung cancer (NSCLC). |
| Study results | PharmaMar | Announced positive results (showing antitumoral activity) of its Phase II study of lurbinectedin (PM1183) in patients with BRCA 1/2 – associated metastatic breast cancer. |
| Startup | PharmaMar | Announced launch of new subsidiary in Austria with the objective of bolstering the company's presence in Europe. |
| Award | Plant Response Biotech | Won award in the agriculture / green biotechnology category at the Europabio Awards 2016. |
| Study launch | Sanifit | Announced Initiation of first clinical trial of SNF472 in Patients with Calciphylaxis. |
| Study results Sanofi | | Regeneron Pharmaceuticals and Sanofi announced publication of positive results in Phase 3 studies evaluating dupilumab in patients with atopic dermatitis. |
| Study launch Spherium Biomed | | Added to pipeline: PeMTADiV (SP15008) a patented preclinical candidate for autoimmune diseases. |
| Distribution agreement | Vytrus Biotech | Signed agreement with Tech Enterprise to distribute its products in 15 African and Middle eastern countries. |
| | | |



November

| Production agreement | 3P Biopharmaceuticals | Signed a production partnership with Neovacs for the manufacture of interferon alpha (IFN $$), a key component for a new therapy developed by Neovacs. |
|----------------------|-----------------------------------|---|
| Study launch | Ability Pharmaceuticals | Announced the initiation of its first Phase 2 Clinical Trial with its novel targeted anticancer agent ABTL0812 to evaluate its efficacy and safety in combination with paclitaxel and carboplatin in 80 patients with advanced or recurrent endometrial cancer or squamous lung cancer. |
| Award | Algaenergy | The European Commission, through the Executive Agency for Small and Medium Enterprises (EASME), has selected AlgaEnergy as one of the SMEs with the greatest growth potential on the continent, within the framework of the Horizon 2020 European Strategic Development Program. |
| Regulatory approval | Amgen | The European Commission approved Parsabiv™ (etelcalcetide) for the treatment of secondary hyperparathyroidism in adults on hemodialysis. |
| Research agreement | Bioingenium and CZ Veterinaria | CZ Veterinary will invest in a new project to use Bioingenium technology for the production of new generation recombinant vaccines to improve the protection of animals against disease. |
| Study results | Biorizon Biotech | Presented results of trials to improve the quality of production for tropical pineapple using spirulina. |
| Product launch | CIBER | Development device capable of reproducing in vitro and by 3D bioprinting the complexity of different tumour types - in order to better understand how they work. |
| Acquisition | Laboratorios Kymos | Acquired Pharmaprogress, an Italian firm specialised in contract research and analysis services. |
| Regulatory approval | Merck | The European Medicines Agency validated the marketing authorization application for Avelumab for the treatment of metastatic merkel cell carcinoma. |
| Research agreement | Neol Bio | Signed a partnership agreement with the U.S. Department of Energy's National Renewable Energy Laboratory (NREL) for the development of microorganisms able to produce fatty alcohols from lignocellulosic sugars. |
| Study results | Oryzon | Presents preliminary safety and efficacy clinical data of its investigational drug ORY-1001, a LSD1 selective inhibitor. |
| Research agreement | Pangaea Oncology | Collaboration with Echevarne for the development of liquid biopsy for cancer patients. |
| Study results | PharmaMar | PharmaMar presents new clinical data for Yondelis® from TAUL study in patients with metastatic or locally relapsed uterine leiomyosarcoma and TR1US study of advanced soft tissue sarcoma (STS) patients. |
| Product launch | Roche Farma | Avastin® (Bevacizumab) become available in Spain, as the first biodrug for advanced cervical cancer, while Cotellic® (Cobimetinib), in combination with Zelboraf® was made available for advanced melanoma. |
| Product launch | StemTek Therapeutics | Launched Cell2Sphere kit: system that tests compounds on cancer stem cells, 3D cell culture drug development and personalised medicine. |



December

| Orphan drug designation | Ability Pharmaceuticals | Received FDA orphan drug designation in the US for ABTL0812, for the treatment of Pancreatic Cancer. |
|-------------------------|-------------------------|--|
| Study results | BCN Health | Cost-effectiveness analysis of insulin degludec compared with insulin glargine for the management of type 1 and type 2 diabetes mellitus - from the Spanish National Health System perspective. |
| Product launch | Biogen | Commercialises two biosimilars in Spain: Benepali and Flixabi, referencing etanercept, by Pfizer, and Remicade, by MSD, respectively. |
| Acquisition | Grifols | Closed acquisition of US firm Hologic's share of NAT donor screening unit. |
| Study concluded | Merck | Concludes CITY study on adherence to treatments to pollen allergies using subcutaneous immunotherapy. |
| Orphan drug designation | Minoryx Therapeutics | Granted Orphan Drug Designation by the EMA for MIN-102: treatment for X-linked Adrenoleukodystrophy (X-ALD), a rare and chronically debilitating, life threatening neurodegenerative disease. |
| Study launch | Nanoimmunotech | Lead SENSO3 project: development of an ozonation treatment system for microcontaminants in water and its monitoring and control by optical biosensors based on gold nanoprisms. |
| Research agreement | N-Life Therapeutics | Collaboration with WAVE Life Sciences to explore cell-specific targeting of nucleic-acid therapeutics in the central nervous system. |
| Accreditation | Pevesa Biotech | Obtained organic production certificate for its rice isolate and hydrolisates. |
| Distribution agreement | PharmaMar | Pharmamar and Chugai Pharmaceutical entered into an agreement for PM1183 in Japan, for various types of tumor. |
| Study launch | Zeclinics | Participates in Horizon 2020's SME instrument programme with "ZeCardio" technology to develop a system of analysis of the cardiovascular effects of drugs in the early research stages. |



Financial environment



Financial environment

6.1. PRIVATE CAPITAL EXPANSION

A total of 26 private capital increase operations involving over \in 63 million have been registered. Overall, the average capital injection per operation was \in 2.4 million. One of the biggest operations involved **Stat Diagnóstica** and reached a total of \in 25 million. If we did not include this operation, the average total per operation would have been just over \in 1.4 million.

| Number of operations | 26 |
|---|-----------------|
| Total volume | 63,489,000.00 € |
| Average total per operation | 2,441,884.62€ |
| Average total per operation (not including largest single operation) | 1,480,346.15 € |

6.2. EQUITY MARKETS

During 2016 two biotechnology companies were listed on the MaB equity market. In July 2016 **Atrys Health** was listed on the MaB after a \in 4.5 million capital increase as part of its IPO. **Pangaea Oncology**, a company specialised in molecular diagnostics and personalised cancer treatment R&D was listed on the MaB towards the end of 2016. Prior to listing, the company successfully completed a €3.8 million capital increase.

This means that a total of seven biotechnology have now been listed on the MaB stock exchange.

Among companies currently listed on the MaB and the *Mercado Continuo* (Spanish stock market) there were six capital increases involving the issuing of shares worth a total of almost \in 17.5 million, meanwhile, capital increases involving debt-equity swaps totalled over three million euros.

royalties. As a result of the \in 1.6 million operation, Inveready now owns over 5% of Bionaturis shares.

CRO **KYMOS Pharma Services** closed the sale of Italian company Pharmaprogress, which has GMP approval from the Italian Medicines Agency.

LipoTruePrimaderm, a company specialised in the manufacturing of ingredients and the commercialisation of cosmetic products acquired 51% of **Ascidea**, a computational biology and genomics company.

6.3. CORPORATE OPERATIONS

Grifols, the Catalan multinational and global producer of plasma-derived protein therapies invested €25 million in **Progenika Biopharma**, meaning that it now owns 89.08% of its capital. It also bought 49% of US company, Interstate Blood Bank, in an €87.9 million operation.

Grupo Bionaturis acquired Zera Intein Protein Solutions (ZIP), a company created in 2015, which commercialised Zera® and Splittera, tools to facilitate the production and purification of biological products. The operation involved an exclusive worldwide licensing agreement for the final development and commercialisation of Splittera® ZIP technology in milestone based payments and sales

6.4. COMPLEMENTARY FUNDING

This section includes complementary funding of biotechnology companies through loans from regional entities offering financial tools such as loans or venture capital, as well as loans from ENISA, a state company controlled by the Ministry of Economy, Industry and Competitiveness, which participates in the funding of promising, innovative business projects.

A total of 33 operations worth €7.7 million were registered.

| Number of operations | 33 |
|------------------------|----|
| Total value 7,695,000. | |



6.5. OTHER OPERATIONS

Towards the end of 2016 **Era7 Bioinformatics** successfully completed 100% of its crowdfunding campaign launched through **Capital Cell** for \in 600,000. The aim of this round was to finance its plan for expansion into the US and to bolster the integration and automation of its cloud based tools. **Bioprognos** raised \in 372,000, also through the Capital Cell platform.

Nostoc Biotech, a company specialised in agricultural biotechnology and a pioneer in the production of biofertilisers using microorganisms from worm humus raised €230,000 from a crowdfunding campaign carried out through the Madrid Stock Exchange.

According to an analysis carried out by ASE-

BIO, the five venture capital management firms specialised in the biotechnology sector

(CRB, Caixa Capital Risc, Ysios Capital, Inver-

eady and Clave Mayor) invested €23.5 million

6.6. VENTURE CAPITAL

across a number of investments in biotechnology companies over 2016. They also pledged a further \in 24 million in future investments.

| Investment 2016 | 23,560,230.00€ |
|-----------------|-----------------|
| Pledged 2016 | 24,189,375.00 € |





Internationalisation





Internationalisation

7.1. SPANISH BIOTECHNOLOGY IN THE GLOBAL CONTEXT

Key Indicators on Biotechnology – OECD

In 2016 the OECD updated its 'Key indicators on Biotechnology' statistics, which compare a number of variables across OECD countries. Some statistics for significant countries such as the UK are not given in the study and data collection methods may vary from country to country. For this reason, it is recommended that OECD data and rankings be used with caution, given the lack of standardisation of the data. It is, nevertheless, a source of useful information that shows the trends of the sector in the international context.

Number of dedicated biotechnology companies: According to the study, in 2014 there were 628 dedicated biotechnology companies in Spain, putting Spain only behind France and the US but ahead of countries including Germany, Italy, Israel and South Korea. The most notable fact is that this means that Spain is growing again in terms of the number of companies, a trend which had stopped since 2013. In total the data shows there are 74 more companies than the previous year.

Biotechnology R&D expenditure: in 2014 Spain once again found itself in 8th position in terms of total biotechnology R&D spending, behind Denmark. 38.3% of R&D investment in biotechnology (2014) in Spain is carried out by small and medium sized companies, a similar percentage to 2013 and still one of the highest among OECD countries, reflecting the large number of SMEs in the sector.

In countries with more mature biotechnology industries, such as the US, Denmark and Switzerland, the number barely reaches the 10% mark.

SCImago Country Rank

In 2015 Spain continued in 10th place in terms of scientific output (all areas) for the

period encompassing 1996-2015. If we only consider the data for 2015, Spain would be in 11th, immediately behind Australia but ahead of science powerhouses including the Netherlands, Russia, Switzerland and South Korea.

In areas related to biotechnology, ranking positions ranged from seventh for 'Agriculture and Biological Sciences'; tenth in Chemistry and Medicine; eleventh in 'Biochemistry, Genetics, Molecular Biology, Neuroscience, Immunology and Microbiology,' and twelfth in Pharmacology, Toxicology and Pharmaceutics.

| TABLE 9. TOTAL SPENDING IN BIOTECHNOLOGY R&D (2014) | |
|---|--|
|---|--|

| COUNTRY | MILLIONS OF USD | YEAR |
|---------------|-----------------|------|
| United States | 38,565.3 | 2014 |
| France | 3,267.9 | 2012 |
| Switzerland | 2,560.0 | 2012 |
| South Korea | 1,414.4 | 2014 |
| Germany | 1,344.0 | 2015 |
| Japan | 1,230.1 | 2010 |
| Denmark | 1,082.2 | 2013 |
| Spain | 801.4 | 2014 |
| Belgium | 660.8 | 2011 |
| Italy | 603.8 | 2014 |
| | | |

Source: OCDE.



7.2. INTERNATIONAL INVESTMENT IN SPAIN

During 2016 biotechnology companies have continued to receive international funding in volumes hitherto not seen in the sector. It is particularly impressive that just over the first quarter of 2017 the amount of international investment has already been greater than during the whole of 2016, more than \notin 70 million by June 2017.

Co-investment continues to be a popular option among large international funds and Spanish entities such as Ysios Capital and Caixa Capital Risc. Most of these investment operations have involved ASEBIO members.

Below is a listing of the biggest operations of 2016 and 2017 (data at the time of publication).





7.3. INTERNATIONALISATION SURVEY

This section looks at the conclusions from the internationalisation survey carried out among biotechnology companies in 2016. The survey, undertaken by ASEBIO, has now taken place for nine consecutive years.

A total of 80.88% of companies surveyed considered internationalisation to be 'essential' for their business activities, practically the same percentage as the previous year (79.3%). When we include those companies which consider internationalisation to be 'important' we can account for 100% of companies surveyed, the first time this has happened since the survey started.

The importance of internationalisation is also reflected in the number of companies which decided to internationalise their activities from the moment of launch, with the percentage climbing from 71.40% last year to 74.55% this year.

7.35% of companies has yet to set out on its internationalisation process. However, 40% of those companies state that internationalisation is a short-term objective which they have not chosen prioritise in order to consolidate their project in the Spanish market first or due to a lack of financial resources.

According to the internationalisation survey, 92.65% of respondents carried out some international activity during 2016, a similar percentage to 2015. Overseas activities by our members are shown on Table 11. 68.42% of ASEBIO member companies now have a specialised international department, marking an increase from the 52% at the previous survey.

The markets most favoured by biotechnology firms are again those in which the sector has matured enough to provide greater business and investment opportunities, such as the European Union (92.45%) and North America (81.63%). Although the UK continues to be part of the EU, only 71.43% of respondents considered it to be a priority market, 20 points below the average for the EU as a whole.

In Asia, Japan is a priority for 50% of respondents, while South Korea loses ground as it goes from being a priority market for 35.71% of respondents to only 16.22%. The prioritisation of South American markets rose the most, particularly Brazil (39%), Mexico (35%), Colombia (30%) and the Southern Cone region of South America (27.5%). It should be noted that Israel continues to be a priority market for the sector (25.64%).

Lack of financial resources was again the main obstacle to internationalisation processes, according to 66.67% of respondents, 7 points less than a year ago.

We should note that this percentage has, however, steadily fallen every year: 73.85% (2015), 79% (2014), 85% (2013), 91% (2012) and 100% in 2009. Other barriers continue to include the lack of training, according to 35.1% of respondents, as well as language barriers (12.28%).

| TABLE 11. MAIN INTERNATIONALISATION ACTIVITIES BY ASEBIO MEMBERS IN 2016 | | |
|--|--------|--|
| Participating in events and fairs | 84.21% | |
| Exporting products and services | 70.18% | |
| Alliances with overseas companies | 64.91% | |
| Investing in branding, communication and marketing | 38.60% | |
| Licensing out | 36.81% | |
| Expanding overseas | 26.32% | |
| Licensing in | 22.81% | |

Source: ASEBIO.

Finally, 94.65% of survey participants feel that the internationalisation process of the biotechnology sector will continue to gain momentum, while only 5.36% believe that internationalisation will remain the same or lose impetus.

7.4. OVERSEAS EXPANSION

37 ASEBIO member companies have an overseas presence, in total spanning 43 markets and 5 continents. The number of overseas subsidiaries has risen to 145, the US hosting the largest number, with 21 ASEBIO members present.

The geographical distribution remains practically identical to that of 2015, with most subsidiaries being in Europe (the EU and Switzerland account for 47% of the total) while South America accounts for 26%:

| Europe | 47% |
|---------------|-----|
| South America | 28% |
| US/Canada | 18% |
| Asia/Oceania | 8% |





TABLE 12. LOCATION OF OVERSEAS SUBSIDIARIES OF ASEBIO MEMBERS

| COUNTRY | NUMBER OF SUBSIDIARIES |
|----------------|------------------------|
| US | 23 |
| United Kingdom | 10 |
| Portugal | 9 |
| Italy | 8 |
| Germany | 8 |
| Mexico | 7 |
| France | 7 |
| Brazil | 6 |
| Switzerland | 5 |
| Belgium | 5 |
| Colombia | 5 |
| Chile | 4 |
| Sweden | 4 |
| Canada | 3 |
| Poland | 3 |
| China | 3 |
| Argentina | 3 |
| Holland | 2 |
| Austria | 2 |
| Peru | 2 |
| Bolivia | 2 |
| Singapore | 2 |

| COUNTRY | NUMBER OF SUBSIDIARIES |
|--------------------|------------------------|
| Denmark | 1 |
| Turkey | 1 |
| Honduras | 1 |
| Dominican Republic | 1 |
| Panama | 1 |
| Paraguay | 1 |
| Guatemala | 1 |
| El Salvador | 1 |
| Costa Rica | 1 |
| Venezuela | 1 |
| Ecuador | 1 |
| Uruguay | 1 |
| Malta | 1 |
| South Korea | 1 |
| Czech Republic | 1 |
| UAE | 1 |
| Slovakia | 1 |
| Australia | 1 |
| Japan | 1 |
| Malaysia | 1 |
| Thailand | 1 |
| Monaco | 1 |

Source: ASEBIO.

Below is the full list of dedicated biotechnology companies who are ASEBIO members and the countries in which they have a presence.

TABLE 13. ASEBIO BIOTECHNOLOGY MEMBER COMPANIES AND COUNTRIES WHERE THEY HAVE A DIRECT PRESENCE

| 2017 | COUNTRY | |
|---------------------------------|--|--|
| ABT, AGAROSE BEADS TECHNOLOGIES | EE.UU. | |
| Almirall | Canada, US, Mexico, Portugal, United Kingdom, France, Italy, Switzerland, Belgium Holland, Germany, Denmark, Austria and Poland | |
| Antares Consulting | Portugal, France, Switzerland, Belgium, Peru, Chile, Brazil and Bolivia | |
| ASPHALION | Germany | |
| Bioseed Capital | United Kingdom | |
| Bioibérica | US, Italy, Poland and Brazil | |
| BIONURE | US | |
| BIOBIDE | US | |
| BTI BIOTECHNOLOGY INSTITUTE | US, Mexico, Portugal, United Kingdom, Italy and Germany | |
| CYTOGNOS | Holland | |
| Era7 Information Technologies | US | |
| Esteve | US, Mexico, Portugal, Italy, China, Sweden and Turkey | |
| | | |



TABLE 13. ASEBIO BIOTECHNOLOGY MEMBER COMPANIES AND COUNTRIES WHERE THEY HAVE A DIRECT PRESENCE (CONT.)

| 2017 | COUNTRY |
|-------------------------------------|---|
| Ferrer | US, Mexico, Portugal, France, Belgium, Germany, Peru, Chile, Brasil, Bolivia, |
| | Colombia, Honduras, Dominican Republic, Panama, Paraguay, Guatemala, El |
| | Salvador, Costa Rica, Venezuela, Ecuador, Uruguay and Argentina |
| Fibrostatin | US |
| GADEA BIOPHARMA | Malta |
| GENOMICA | China and Sweden |
| GRIFOLS | Canada, US, Mexico, Portugal, United Kingdom, France, Italy, Switzerland, Germany |
| | Poland, Chile, Brazil, China, Sweden, Colombia, Argentina, Czech Republic, UAE, |
| | Slovakia, Australia, Japan, Malaysia, Singapore and Thailand |
| GRUPO NORAYBIO | France and Italy |
| INKEMIA IUCT GROUP | Brazil and Colombia |
| Insights in Life Sciences (iIS) | United Kingdom |
| Intelligent Pharma | Canada, US, United Kingdom and Germany |
| Inveready | US |
| KYMOS PHARMA SERVICES | Italy |
| Laboratorios LETI | US, Portugal and Germany |
| Lipopharma Therapeutics | US |
| MABXIENCE | Switzerland and Argentina |
| MeDiNova Investigación y Desarrollo | United Kingdom |
| NATAC BIOTECH | US and Chile |
| Neuron Bio | US |
| NIMGENETIS | Mexico and Brazil |
| Oryzon Genomics | US |
| Pharmamar | US, United Kingdom, France, Italy, Switzerland, Belgium, Germany and Austria |
| Pharmaphenix | US and South korea |
| Praxis Pharmaceutical | Portugal, France and Colombia |
| RJ BIOTECH SERVICES | US, Portugal, United Kingdom, Belgium, Sweden, Singapore and Monaco |
| SANIFIT | US |
| Science & Innovation Link Office | Colombia |
| Sermes CRO | United Kingdom |
| SISTEMAS GENÓMICOS | Mexico |
| SOM Biotech | US |

Source: ASEBIO.

7.5. INTERNATIONAL ALLIANCES

Over the course of 2016, ASEBIO has identified a total of 71 international alliances, compared to 54 in 2015, a 31% year-on-year increase. The geographical distribution is similar to other years, with the focus being on other european countries (51% of the total), the US (27%), Asia (15%) and South America (7%).

These figures include all formal agreements between any Spanish company or institution and international entities involving an explicit agreement for a shared objective of any nature (be it R&D, production, sales or other areas).





Valorisation of biorefinery by-products leading to closed loop systems with improved economic and environmental performance

Sustainable and economically viable integrated closed loop biorefineries – with improved economic and environmental benefits – are the result of knowledge transfer, biotechnologies and products delivered by the Valor-Plus project.

- Development of quality control procedures for the reliable and consistent recovery of minimally degraded hemicellulose and lignin fractions through a novel biorefining process
- Development of cutting edge biotechnological processes for the selective conversion of hemicellulose and lignin fractions as well as crude glycerol to high value product streams
- Demonstration of the profitability of sustainable and economically viable closed-loop integrated biorefineries for the valorisation of lignocellulose and glycerol via the production of high value product streams
- The final outcome is increased commercial competitiveness and profitability through improved efficiency of the processes and sustainable use of a wider range of biomass resources.

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Who is who?





Who is Who? – Asebio Members

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ABILITY PHARMACEUTICALS, S.L.



ACKERMANN EXECUTIVE



ALEXION PHARMA SPAIN, S.L.



ALLINKY BIOPHARMA







ABT, AGAROSE BEAD TECHNOLOGIES



AGRENVEC



ALGAENERGY, S.A.



ABBVIE



AC-GEN READING LIFE



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AYMING



BCN HEALTH



BIFROST HEALTH





BAYER CROPSCIENCE NV

BEST MEDICAL DIET



BBD BIOPHENIX - BIOBIDE (GRUPO BNT)



BIOFABRI

BIOCROSS











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BIOIBERICA

BIOIBÉRICA, S.A.



BIOGENETICS

ingenium

bio



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BIOMEDAL, S.L.



BIONCOTECH THERAPEUTICS, S.L.



BIONURE



BIOMAR



BIOINGENIUM, S.L.

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BIONATURIS GROUP



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BIONOS BIOTECH, S.L.





BIORAW





BIORIZON BIOTECH, S.L.



BIOTOOLS B&M LABS, S.A.





BIOSERENITA

BIOSEARCH, S.A.

BOSQUES NATURALES

BOSQUES NATURALES, S.A.



BRISTOL MYERS SQUIBB





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CELGENE INSTITUTE OF TRANSLATIONAL RESEARCH EUROPE (CITRE)







CRB INVERBIO, S.G.E.C.R.

CYTOGNOS, S.L.

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DREAMGENICS, S.L.





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NEURON BIO



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